SERVICE MANUAL
SIGMA INTERNATIONAL
MODEL 8000 & 8000 *Plus*
INFUSION PUMPS
44000
REVISION M June 2007

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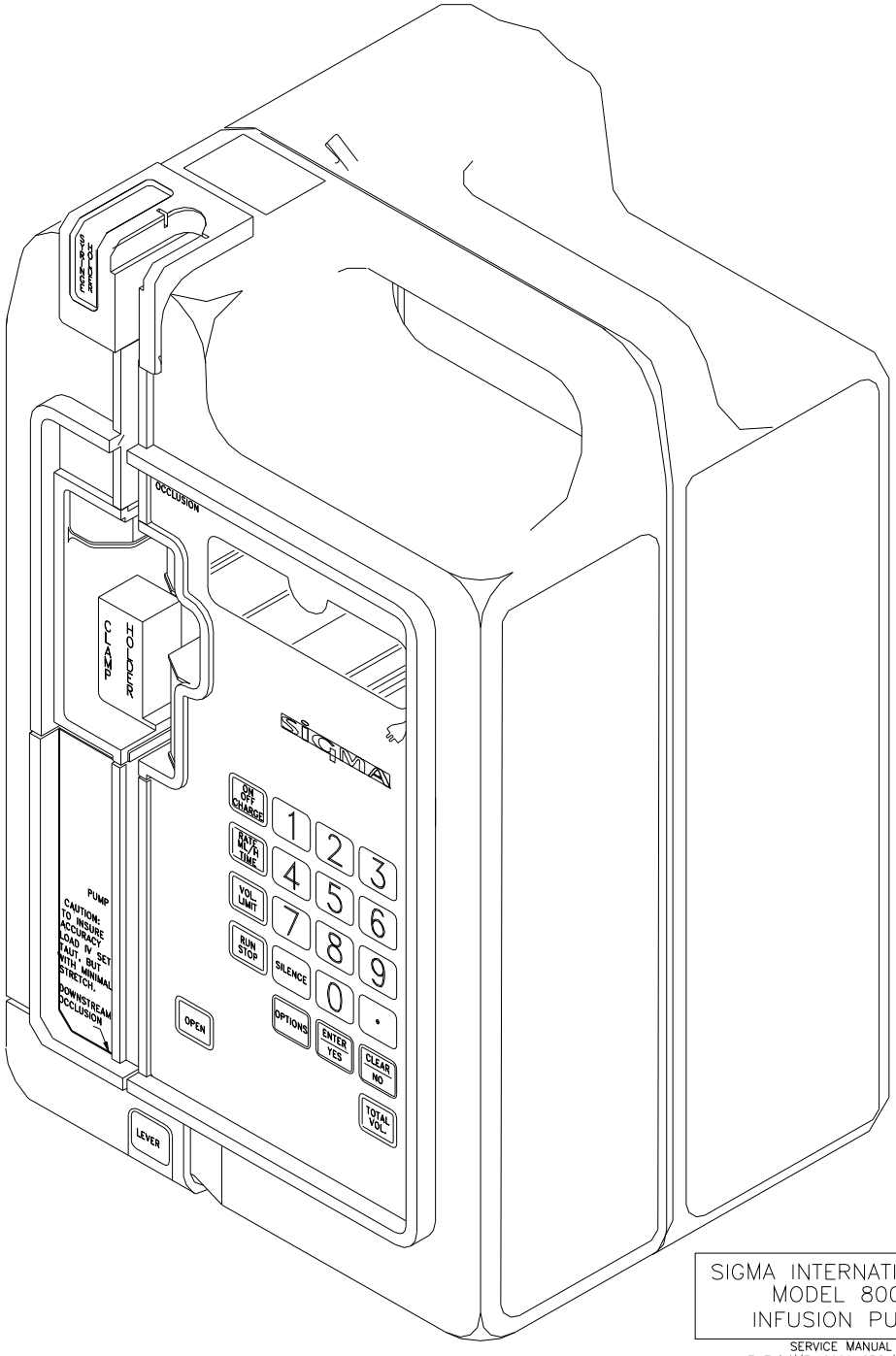

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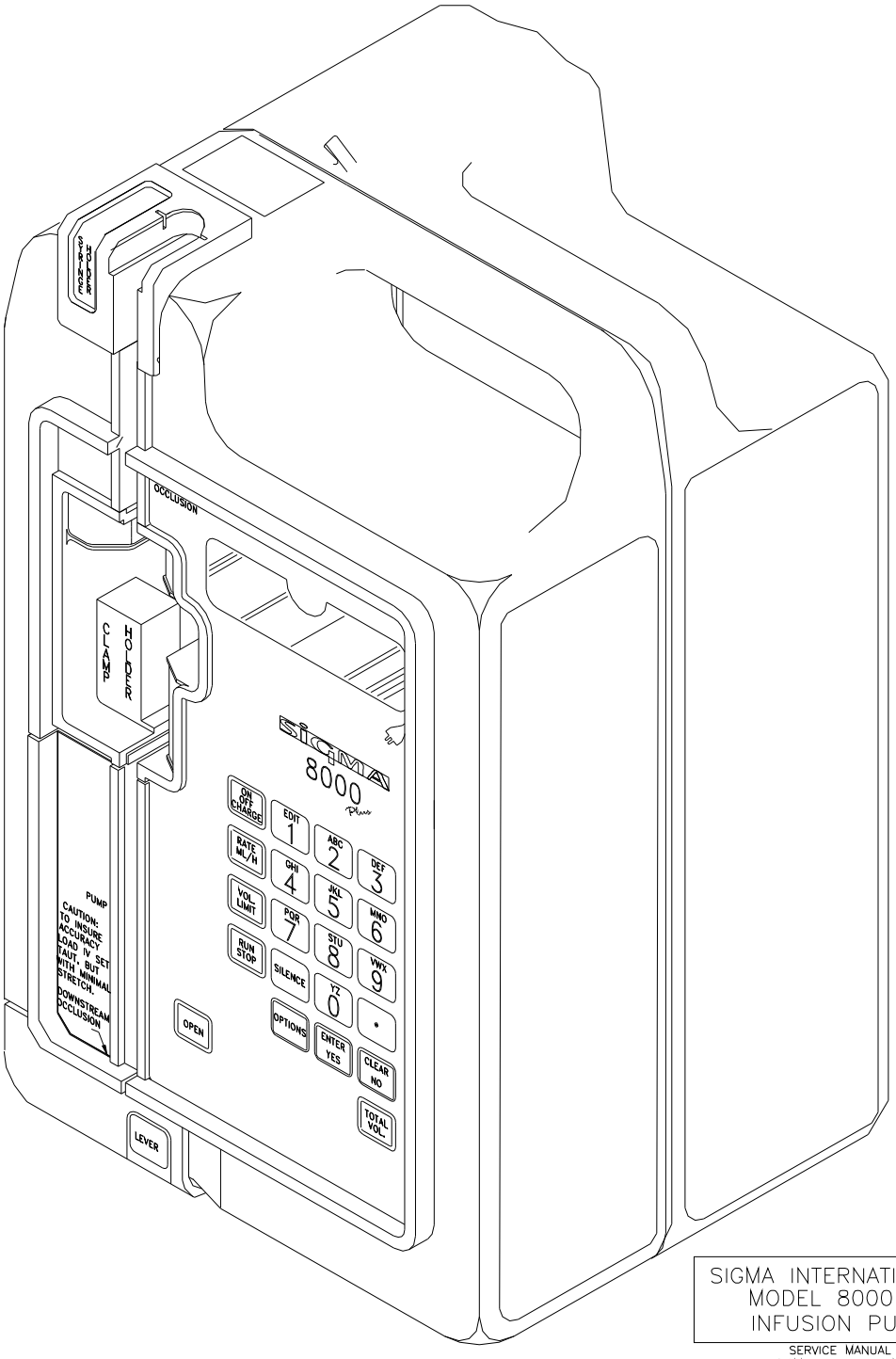

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SERVICE MANUAL
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SECTION 1

SIGMA MODEL 8000 & 8000 *Plus* INFUSION PUMP - SERVICE MANUAL REV. M
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1.1 MODEL 8000 INFUSION PUMP LIMITED WARRANTY

SIGMA International warrants, to the original purchaser, the SIGMA 8000 Infusion Pump (hereinafter Pump) to be free from defects in material and workmanship under normal use and service for one year from the date of purchase. SIGMA's obligation under this limited warranty shall be limited to repair or replacement of Pumps, which, upon SIGMA's examination, are found defective in material or workmanship under normal use and service within one year from the date of purchase by the original purchaser. The repair or replacement of any Pump under this limited warranty shall not extend the term of this limited warranty beyond the original term as set forth in this paragraph.

Qualified, trained service personnel must perform all repairs qualifying under this limited warranty. In the event that any Pump is found to be defective during the aforesaid warranty period, the purchaser shall notify SIGMA in writing of any claimed defect within thirty days after such claimed defect is discovered. The Pump claimed to be defective must then be promptly delivered to SIGMA or its designated representative for inspection and repair or replacement, if necessary. Pumps returned to SIGMA must be properly packaged and sent to SIGMA with postage and handling prepaid. Severe pump damage may result if SIGMA shipping cartons and inserts are not used. Shipping cartons and inserts are available from SIGMA.

This limited warranty shall not apply to defective conditions or damage caused, in whole or in part, by negligence, fluid spills, dropped Pumps, misuse, abuse, improper installation, improper cleaning, alteration, or damage caused by improper shipment to SIGMA. If, after inspection, SIGMA is unable to identify a problem, SIGMA reserves the right to invoice the purchaser for such inspection. Annual Preventative Maintenance Inspections are also excluded from this warranty.

THIS LIMITED WARRANTY IS THE SOLE AND ENTIRE WARRANTY PERTAINING TO THE PUMP AND IS IN LIEU OF AND EXCLUDES ALL OTHER WARRANTIES OF ANY NATURE WHATSOEVER WHETHER EXPRESS, IMPLIED OR ARISING BY OPERATION OF LAW, TRADE, USAGE OR COURSE OF DEALING, INCLUDING, BUT NOT LIMITED TO, WARRANTIES OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE. ANY AFFIRMATION OF FACT OR PROMISE MADE BY SIGMA SHALL NOT BE DEEMED TO CREATE AN EXPRESS WARRANTY THAT THE PUMP SHALL CONFORM TO THE AFFIRMATION OR PROMISE; ANY DESCRIPTION OF THE PUMP IS FOR THE SOLE PURPOSE OF IDENTIFYING IT AND SHALL NOT BE DEEMED TO CREATE AN EXPRESS WARRANTY THAT THE PUMP SHALL CONFORM TO SUCH DESCRIPTION; ANY SAMPLE OR MODEL IS FOR ILLUSTRATIVE PURPOSES ONLY AND SHALL NOT BE DEEMED TO CREATE AN EXPRESS WARRANTY THAT THE PUMP SHALL CONFORM TO SUCH SAMPLE OR MODEL; AND NO AFFIRMATION, PROMISE, DESCRIPTION SAMPLE OR MODEL SHALL BE DEEMED TO BE PART OF THE PURCHASE OF THE PUMP. THE PURCHASER EXPRESSLY ACKNOWLEDGES THAT THIS LIMITED WARRANTY CONSTITUTES THE PURCHASERS SOLE AND EXCLUSIVE REMEDY WITH RESPECT TO ANY CLAIM OF THE PURCHASER ARISING OR RESULTING DIRECTLY OR INDIRECTLY FROM THE USE OF THE PUMP. IN NO EVENT SHALL SIGMA BE LIABLE HEREUNDER FOR AN AMOUNT THAT EXCEEDS THE PURCHASE PRICE OF THE PUMP. NO PERSON, FIRM OR CORPORATION IS AUTHORIZED TO ASSUME FOR SIGMA ANY LIABILITY IN CONNECTION WITH THE SALE OF THE PUMP.

1.2 MODEL 8000 INFUSION PUMP DANGERS, WARNINGS AND CAUTIONS

DANGER:

- RISK OF EXPLOSION IF USED IN THE PRESENCE OF FLAMMABLE ANESTHETICS.
- RISQUE D'EXPLOSION. NE PAS EMPLOYER EN PRESENCE D'ANESTHESQUES INFLAMMABLES.
- ELECTRIC SHOCK HAZARD. NO USER SERVICEABLE PARTS. DO NOT OPEN DEVICE COVER. REFER SERVICING TO QUALIFIED SERVICE PERSONNEL.

WARNING:

- RISK OF FIRE. REPLACE FUSES AS MARKED.
- ANY PUMP THAT HAS BEEN DROPPED OR IS OTHERWISE VISIBLY DAMAGED MUST NOT BE USED. Discontinue use immediately and refer to a qualified Service Technician for inspection and repair prior to further use.
- USE ONLY I.V. ADMINISTRATION SETS THAT ARE LISTED ON SIGMA COMPATIBLE SET LISTING (contact SIGMA for listing).
  NOTE: Use of any other sets will result in malfunction or inaccurate delivery.
- DO NOT USE IF ROOM OR PUMP TEMPERATURE IS BELOW 15°C (60°F) OR ABOVE 40°C (104°F).

CAUTION:

- LITHIUM BATTERY (SIGMA P/N 55003)
  (LOCATION: BT1 ON PCBA P/N 60010)
  DANGER OF EXPLOSION IF THE BATTERY IS INCORRECTLY REPLACED. REPLACE ONLY WITH THE SAME OR EQUIVALENT TYPE RECOMMENDED BY SIGMA. DISCARD USED BATTERIES ACCORDING TO THE MANUFACTURER'S INSTRUCTIONS.

ATTENTION:

- LITHIUM BATTERY (SIGMA P/N 55003)
  (LOCATION: BT1 ON PCBA P/N 60010)
  IL Y A DANGER D'EXPLOSION S'IL Y A REMPLACEMENT INCORRECT DE LA BATTERIE. REMPLACER UNIQUEMENT AVEC UNE BATTERIE DU MEME TYPE OU D'UN TYPE RECOMMANDE PAR SIGMA. METRE AU REBUT LES BATTERIES USAGEES CINFORMENT AUX INSTRUCTIONS DU FABRICANT.

CAUTION:

- Federal (USA) law restricts this device to sale by or on the order a physician or other licensed practitioner.
- Operate only on the AC Line voltage for which the unit is marked.
- Use only a Hospital Grade outlet for AC operation to assure proper grounding.
- The pump should be plugged in during storage to maintain proper battery charge.

- Remove AC power and disconnect the battery connector prior to servicing this Pump.

CAUTION:

- Routine cleaning and periodic maintenance is needed to assure that the Pump remains safe and functional. Refer to Section 1.3, Cleaning and Maintenance, and Section 1.5, Preventative Maintenance.

- Solution spills should be cleaned up, as soon as possible, using a damp cloth or sponge. Dry thoroughly before use. The upstream sensors tube channel must be kept clean and dry at all times during pump operation. Do not use hard or sharp objects to clean sensor tube channel areas. Failure to comply with this requirement may cause the pump to fail. Refer to Section 1.3, Cleaning and Maintenance.

- Static sensitive electronics used in SIGMA infusion pumps may be damaged by electrostatic discharge. Service technicians must follow proper ESDS procedures when working on units. Refer to MIL-STD-1686 for protective handling procedures.

- Do not use a pen or any other sharp object to actuate the keyboard switches. Replace torn or punctured membranes immediately, to assure solutions won't internally damage the membrane switch and prevent proper operation of the Model 8000. (Replacement should only be performed by authorized personnel).

- If using filter set, use only filters which state specifically in the instructions that they may be used with pumps. Read and follow instructions of the filter to be used.

1.3 MODEL 8000 CLEANING AND MAINTENANCE

1. CAUTION - Always press STOP then OFF and unplug the mains cord before cleaning.

2. CAUTION - DO NOT sterilize by autoclaving, ETO gas, or spraying. DO NOT immerse any part of the pump. DO NOT use abrasive cleaners.

3. CAUTION – Do not use phenolic based cleaners or disinfectants, extended use may cause damage to the keyboard, case and any other plastic component of the Model 8000.

4. Clean exterior surfaces with pump in upright position. Apply cleaners with a dampened cloth per manufacture's instruction and dilution ratios.
   A lint free, foam-tipped swab (Chemtronics Foamtip (TM), for example) may be used in the Tube Channel.

5. Visually inspect the tubing channel and remove any foreign material. Blocked tube channel could cause accidental free flow.

6. Cleaning FLOW SENSORS (drop sensors): Clean FLOW SENSOR and PUMP FLOW SENSOR CONNECTOR with a small amount of isopropyl alcohol and a cotton swab. USE OF ELECTRICAL CONTACT CLEANERS WILL CAUSE DAMAGE TO THESE PARTS.

7. Subsequent disinfecting is recommended using the same application technique. Disinfectants should remain on the pump surface in an even, but not dripping, film for the manufactures' recommended contact time. Wipe dry or air-dry after completion of contact time period before pump reuse.

8. Dispose of all cleaning/ disinfectant materials per federal, state and local regulations for infectious waste disposal.

9. The following cleaners and disinfectants may be used:
   - 70% to 90% ethyl or isopropyl alcohol in water. *
   - 10% bleach in water (produces 0.55% Sodium Hypochlorite)
   - Sodium Hypochlorite cleaner disinfectant such as:
   - Dispatch TM ** by Caltech Industries, Inc (1-800-234-7700)

* Alcohols are flammable and should be used in a well-ventilated area.

** The selection and use of disinfectants should be in accordance with hospital and user facility polices. This listing is strictly provided to indicate pump material compatibility with cleaning and disinfectant agents.

1.4 MODEL 8000 INFUSION PUMP SPECIFICATIONS

1.4.1 APPLICATIONS

- Large and small volume parenterals
- Neonatal
- Homecare
- Blood infusions and Epidural applications

1.4.2 ADMINISTRATION SET

Compatible with standard gravity IV sets supplied by Hospira, Baxter and B.Braun/McGaw (all three are registered trademarks) and several other companies (consult SIGMA for a complete list of compatible standard IV sets and syringes).

1.4.3 PERFORMANCE

When using IV bags or bottles*, flow rate accuracy is nominal ±5% from 2-999 ml/hr, and ±10% from 0.1-1.9 ml/hr. Flow rate accuracy for Securus AN tubing is 5% Accuracy 2 - 100 mL/hr, ± 6% Accuracy >100 - 400 mL/hr, ± 8% Accuracy >400 - 999 mL/hr.

This is based upon;

- Minus 100 mmHg maximum negative downstream pressure.
- Plus 100 mmHg maximum positive downstream pressure.
- With 72 hour usage of one section of an IV set, while infusing a maximum of 9 liters (i.e. 125 ml/hr).
- With the solution 24 in. above the pumping mechanism.
- Using the single standard IV set brand specified for the pump (approved Hospira, Baxter or B. Braun/McGaw sets).
- Minimum 60-minute sample volumes (contact SIGMA for detailed trumpet curves).
- Nominal temperature range from 68°F to 75°F.
- Sets loaded taut with minimal stretch during loading (excessive set stretching can cause 10% flow errors).

Note: If these parameters are exceeded, move to a fresh section of tubing to restore specified accuracy.

- 0.1-999 ml/hr delivery range (RATE), with 0.1 ml/hr increments from 0.1-99.9 ml/hr and 1.0 ml/hr increments above 100 ml/hr.
- 0.1-9999 ml volume limit range.

***Note:** IV bottle usage requires a vented IV set.

KVO (keep vein open) rate is 1 ml/hr or the selected rate, whichever is lower.

IV set based anti-free flow protection.

Upstream occlusion time to alarm:

DISTANCE OCCLUSION ABOVE PUMP

RATE	6 IN.	24 IN.
5 ml/hr	< 4 min.	< 8.min
100 ml/hr	< 30 sec.	< 40 sec.
999 ml/hr	< 10 sec.	< 10 sec.

Note: Upstream occlusion detection is only effective for occlusions present immediately after the start of the pump's run operation.

Downstream occlusion time to alarm:

With Occlusion 45 in. below the pump and alarm set to:

RATE	2 PSI	10 PSI	15 PSI
1 ml/hr	< 20 min.	< 40 min.	< 60 min.
100 ml/hr	< 15 sec.	< 20 sec.	< 30 sec.
Max Bolus	0.34 ml	0.6 ml	0.7 mil

Downstream occlusion time to alarm for Securus AN tubing:

With Occlusion 45 in. below the pump and alarm set to:

RATE	2 PSI	10 PSI	15 PSI
1 ml/hr	< 20 min.	< 80 min.	< 110 min.
100 ml/hr	< 15 sec.	< 30 sec.	< 30 sec.
Max Bolus	0.34 ml	0.7 ml	0.8 mil

Occlusion pressure is adjustable from 2 - 15 PSI.

Specifications for downstream occlusion are:

Pressure setting	Trip pressure tolerance
2 psi	+2, -1 psi
3 to 4 psi	+2, -1.5 psi
5 to 15 psi	±2 psi

Mechanical occlusion pressure limit under fault conditions (the maximum pumping pressure if the occlusion alarm is inoperative) - 55 PSI.

The air detector senses air bubbles > 1 inch long in the IV set.

All safety related sensing systems are automatically checked for proper operation at power on and periodically thereafter. Faults are identified by FIX code.

1.4.4 TECHNICAL

Type of pump - Volumetric infusion pump.

Operating Principle - Linear peristaltic

Rated voltage and current:
105-135 VAC (0.5A), 50/60 Hz, fused T500ma (IEC 127) - U.S.
220/240 VAC (0.25A), 50/60 Hz, fused T250ma (IEC 127) - European.

Ground impedance <.13 ohms (per UL544 or CSA C22.2 No. 4)

Patient leakage: < 25 microamps, normal condition;
< 50 microamps, single fault condition.

Electro magnetic compatibility immunity and emissions:
In compliance with IEC 601-1-2 and IEC 601-2-24 (1st edition 1993-04).

Operating conditions:
Relative humidity: 30-90% (non-condensing)
Temperature: 65 - 85°F
Atmospheric pressure: 22 - 31 in. Hg

Battery:
Type: 12-volt battery pack consisting of (6) 2V/2.5 amp hr rechargeable sealed lead acid batteries.

*Operation: >4.5 hrs to LOW BATTERY indication, >30 min. from LOW BATTERY to PLUG IN alarm.
Recharge time: >18 hrs

* **NOTE:** Specification for batteries in “as new” condition.

Computer interface: RS232 port on the back panel. This connector is also used to connect the pump to staff call systems. Since the systems pumps may be connected to vary widely, users should consult with SIGMA's Service Department for specific instructions. Users without sufficient electronic background and knowledge of both the SIGMA 8000 infusion pump and outside devices it may be connected to should never attempt such a connection. To do so otherwise can result in severe damage to the pump.

Staff Call System
Contact Closure:
Rated Load 0.50A at 125VAC, 1A at 24VDC.

Flow Sensor (Drop Sensor): The Flow Sensor detects drop flow in the IV set's drip chamber. The sensor fits on the drip chamber and its cord plugs into the pump's RS232 connector (back panel). When the sensor detects no drop flow, the EMPT BOTT/CLR ↑OCC (empty bottle/upstream occlusion) alarm occurs. Eliminating the cause of the alarm and pushing RUN causes the infusion to resume.

Alarms:
- Air
- Downstream Occlusion
- Upstream Occlusion
- Infusion Complete
- Program Complete
- Low Battery/Plug In
- Malfunctions
- Empty Container (with optional flow sensor)
- Operator Errors/Prompts
- PM Due Notification

1.4.5 PHYSICAL

Dimensions:

- 9.5" H x 6.5" W x 6.75" D
- (242 mm x 165 mm x 174 mm)

Weight:

- 10 lbs. (4.5 Kg)

Case material:

- High impact plastic (UL listed/CSA certified)

IV Pole Clamp Pole Size Requirement

- 0.5” to 1.0” diameter

1.4.6 LISTINGS & CERTIFICATIONS

NRTL/C, to CSA Standard C22.2 No. 125-M1984, Electromedical Equipment and UL Standard No. 544, Medical and Dental Equipment.

The "NRTL/C" indicates that the product has been evaluated by CSA to the applicable ANSI/UL and CSA Standards, for use in the U.S. and Canada. NRTL (Nationally Recognized Testing Laboratory) is a designation granted by the U.S. Occupational Safety and Health (OSHA) to laboratories, which have been recognized to perform certification to the U.S. Standards.

1.0 PURPOSE

The purpose of this procedure is to provide a guideline for the Preventative Maintenance of the SIGMA 8000 and 8002 IV pumps. This procedure may be used as an incoming check out procedure.

2.0 SCOPE

The guidelines are to ensure that the SIGMA 8000/8002 IV pumps are operating within the specified parameters set forth by SIGMA International, Inc.

3.0 REFERENCES

ICL 35001PM – Preventative maintenance check off sheet
ICL 13000 – Field Procedure for Onboard Flow Calibration, Model 8000 IV Pump.

4.0 EQUIPMENT

4.1 SIGMA 8000 or 8002 Infusion Pump
4.2 IV set of the brand specified on the pump label
NOTE: If the pump is being accuracy tested following a clinical problem, it is essential to test with an IV set of the same catalog number and lot number as that in use when the problem occurred.
4.3 IV container (250, 500 or 1000 ml), filled with water, to be used as pumping source.
4.4 Collection vessel to be class "A" 100 ml graduate (any 100ml collection vessel may be used if scale is used for flow rate accuracy measurement).
4.5 Pressure gauge
4.6 Line Safety Analyzer
4.7 Electronic balance with at least 0.01 gram precision.
4.8 Collection cup.
4.9 A cloth or paper towel.

5.0 DOCUMENTATION

5.1 After each operation in this procedure, record the findings on ICL 35001PM.

6.0 PROCEDURE

NOTE: WHEN INSPECTING THE MODEL 8002, REPEAT STEPS 6.2 THRU 6.10 FOR BOTH CHANNELS, INDICATING THE CHANNEL INSPECTED ON ICL 35001PM.

NOTE: The brand of IV sets being tested must be compatible with the pump under test. The proper IV set calibration is listed on the label located on the top of the pump.

6.1 PREVENTATIVE MAINTENANCE SCHEDULE
- 6.1.1 Preventative maintenance is recommended a minimum of once annually on all pumps in service.
- 6.1.2 Preventative maintenance should be performed after any user facility maintenance.
- 6.1.3 Preventative maintenance test should also be carried out whenever a pump is dropped, or suspected of having been otherwise damaged.
- 6.1.4 A PM DUE alarm may be set as indicated in section 6.15 of this procedure.

6.2 VISUAL INSPECTION
- 6.2.1 Inspect the pump for visual evidence of damage and or defects to exterior components (i.e. case, membrane and lever).
- 6.2.2 The IV set tube channel must be free of foreign materials and dry for both testing and use.
  - 6.2.2.1 Any evidence of damage to these parts is reason to run the preventative maintenance checks.
- 6.2.3 Verify legibility of all labels.

6.2.3.1 Replace labels as necessary.

6.3 VISUAL INSPECTION FOR MODEL 8002 ONLY

6.3.1 Inspect the both channels of the pump for visual evidence of pump body cracks:

6.3.1.1 Fully open the levers.

6.3.1.2 Observe the back walls of the tubing channels shown as hatched Area A and Area B on the Fig.1 (i.e. areas between roller clamp holders and lever assemblies) using directional light. Any evidence of cracks on these areas is reason to return the pump to the factory for service.

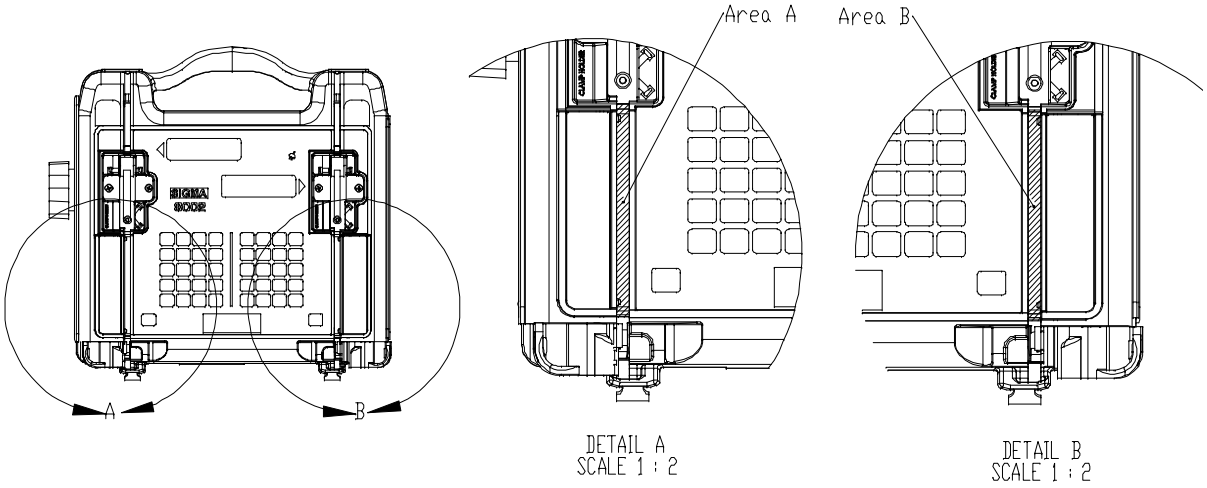

Fig.1

6.4 KEYBOARD TEST

6.4.1 The Model 8000 keyboard and displays may be checked for proper operation as follows:

6.4.1.1 Press the “ON/OFF” key to turn the unit on and observe that the displays indicate “8888 8888”.

6.4.1.2 Press the “RATE” (ML / H) key followed by the “1”, “2”, and “3” keys and observe the display to be “RATE 123”.

6.4.1.3 Press the “RATE” (ML / H) key followed by the “4”, “5” and “6” keys and observe the display to be “RATE 456”.

6.4.1.4 Press the “VOL LIMIT” key followed by the “7”, “8” and “9” keys and observe the display to be “VOL 789”.

6.4.1.5 Press the “VOL LIMIT” key followed by the “9”, “0”, and “.” keys and observe the display to be “VOL 90.0”.

6.4.1.6 Press the “VOL LIMIT” key followed by the “CLEAR” key and observe the display to be “VOL 0”.

6.4.1.7 Press the following keys and observe the associated displays:

6.4.1.7.1 “OPTIONS” key, display sequence is “SET” “OPTION CODE”, “9” key; display is “OPT 9”.

6.4.1.7.2 “9” key, display is “OPT 99”

6.4.1.7.3 “ENTER” key, display is “ALL CLEAR”, the pump will return to normal operation.

6.4.1.7.4 Prime a set and load the roller clamp (closed) into the pump.

6.4.1.7.5 Press the “OPEN” key and finish loading the set into the pump.

6.4.1.7.6 Set the rate to 999 and the volume to 1.0.

6.4.1.7.7 Press the “RUN / STOP” key, let the pump run to infusion complete.

6.4.1.7.8 Press the "RUN / STOP" key to stop the pump.
6.4.1.7.9 Press the "TOTAL VOLUME" key; observe the display is "TOTL 1.0".

6.5 UPSTREAM (PROXIMAL) OCCLUSION SENSOR TEST
- 6.5.1 Set rate to 100 ml / hr.
- 6.5.2 Set volume to 1 ml.
- 6.5.3 Occlude IV set 12" above the pump with a slide clamp or pair of hemostats.
- 6.5.4 Push the "RUN / STOP" key to start the pump.
- 6.5.5 Verify the pump goes into "CLR ↑ OCC / CLR AIR" alarm prior to infusion complete message.

6.6 AIR DETECTION TEST
- 6.6.1 Set volume limit to 50 ml.
- 6.6.2 Push the "RUN / STOP" key.
- 6.6.3 Introduce a 1 1/8' air bubble upstream from the pump.
- 6.6.4 Verify the pump goes into "CLR AIR / CLR ↑ OCC" alarm.

6.7 DOWNSTREAM (DISTAL) OCCLUSION SENSOR TEST
- 6.7.1 Enter option 70 by pressing the "OPTION" key and "70", and "ENTER".
  - 6.7.1.1 Verify the downstream occlusion trip pressure setting (if set to less than 15psi [750mmHg], set equal to 15psi [750mmHg]).
- 6.7.2 Record pressure setting
- 6.7.3 Set volume limit to 1 ml.
- 6.7.4 Connect a pressure gauge to the end of the IV set with a length of 4' to 5' of tubing between the pump and gauge.
- 6.7.5 Push the "RUN / STOP" key to start the pump.
- 6.7.6 Verify the pump goes into "CLR ↓ OCC" alarm at a pressure within +/- 2 psi or +/- 100 mmHg of the occlusion trip pressure setting.
- 6.7.7 If occlusion trip pressure setting was changed in step 6.7.1.1, then reset to PSI changed from using option 70.

6.8 MEMORY TEST
- 6.8.1 Turn the pump on.
- 6.8.2 Set a parameter for "RATE" and "VOL LIMIT".
- 6.8.3 Turn the pump off.
- 6.8.4 Turn the pump on and verify the parameters were saved.

6.9 LOW FLOW RATE ACCURACY TEST FOR MODEL 8002 ONLY
- 6.9.1 Test should be done for both channels of the pump.
- 6.9.2 Materials required – See section 4.0 steps 4.1- 4.4, 4.7-4.9.
- 6.9.3 Test data – Flow rate (ml / hr) selected for test……..10 ml / hr.
  Pump vol. Limit (ml) (length of test)……10 (1 hr.).
  Optimal actual volume pumped ..……...10 ml.
  Pass criteria: acceptable volumes……...9.5 – 10.5 ml.
- 6.9.4 A 1 hour warm up period, running with a tube installed, is recommended for the pumps before flow rate testing (Ref IEC601-2-24).
- 6.9.5 Hang the IV container, filled with water, 24" above the pumping mechanism.
- 6.9.6 Connect the IV set to the IV container and prime the set completely.
  - 6.9.6.1 Remove all air from the tubing, being sure the drip chamber is at least half full.
- 6.9.7 Load a new / fresh section of the set into SIGMA 8002 pump and close the lever.
  - 6.9.7.1 Open the roller clamp.
- 6.9.8 Place the open end of the IV set over a dry collection cup.
  - 6.9.8.1 Be sure fluid is at the end of the IV set, but none has dripped into the collection cup before starting the test.
- 6.9.9 Turn the pump on, and set the flow rate = 10 ml / hr and set volume limit = 10 ml.
- 6.9.10 Begin the test by pressing the "RUN" key.
- 6.9.11 Allow the SIGMA 8002 pump to run until it goes into infusion complete alarm.
  - 6.9.11.1 Press the "STOP" key to halt the KVO (keep vein open) rate once the pump goes into infusion complete.
  - 6.9.11.2 If test is interrupted by any alarms, start this test again from the beginning.

6.9.12 When delivery is complete, weigh the fluid using an electronic balance.
- 6.9.12.1 Weigh the collection cup with fluid in it.
- 6.9.12.2 Zero the electronic balance while fluid is in the cup.
- 6.9.12.3 Remove the collection cup. Empty the cup and dry the inside with a cloth or paper towel.
- 6.9.12.4 Weigh the empty cup. This value multiplied by negative one (-1) is the weight of the fluid collected.

6.9.13 If this weight is within the range 9.5 – 10.5 g, the pump is properly calibrated. Otherwise - return the pump to SIGMA International, Inc., or perform the flow rate calibration procedure according to CTP 13000 when flow rate error is not greater than 8% and repeat the Low Flow Rate Accuracy Test.

6.10 RECOMMENDED FLOW RATE ACCURACY TEST

6.10.1 Materials required – See section 4.0 steps 4.1- 4.4.

6.10.2 Test data – Flow rate (ml / hr) selected for test …….100 ml / hr.
Collection vessel……...Class A Graduate, 100 ml.
Pump vol. Limit (ml) (length of test)…….50 (30 min.).
Optimal actual volume pumped (ml)……...50 ml.
Pass criteria: acceptable volumes……...47.5 – 52.5 ml.

6.10.3 A 1 hour warm up period, running with a tube installed, is recommended for the pumps before flow rate testing (Ref IEC601-2-24).

6.10.4 Hang the IV container 24” above the pumping mechanism

6.10.5 Connect the IV set to the IV container and prime the set completely.
- 6.10.5.1 Remove all air from the tubing, being sure the drip chamber is at least half full.

6.10.6 Load a new / fresh section of the set into SIGMA 8000 pump and close the lever
- 6.10.6.1 Open the roller clamp

6.10.7 Connect the end of the IV set to the collection vessel.
- 6.10.7.1 If the vessel is a 100 ml graduate, locate the end of the set around the 60ml level.
- 6.10.7.2 Be sure fluid is at the end of the IV set, but none has dripped into the graduate before starting the test.

6.10.8 Turn the pump on, and set the flow rate = 100 ml / hr and set volume limit = 50 ml.

6.10.9 Begin the test by pressing the “RUN” key.

6.10.10 Allow the SIGMA 8000 pump to run until it goes into infusion complete alarm.
- 6.10.10.1 Press the “STOP” key to halt the KVO (keep vein open) rate once the pump goes into infusion complete.
- 6.10.10.2 If test is interrupted by any alarms except air, the test can be continued as long as the pump was observed by the tester to have not been in “STOP” for more than ten minutes.

6.10.11 Observe the actual volume collected, either visually or weighed on the scale.
- 6.10.11.1 When measuring fluid level visually in the graduate, the level is read from the bottom of the fluid meniscus.
- 6.10.11.2 When measuring with the scale (gravimetric method):
  - 6.10.11.2.1 Weigh the collection vessel and water.
  - 6.10.11.2.2 Empty and dry the collection vessel.
  - 6.10.11.2.3 Weigh the collection vessel. The difference between the two measured weights is equivalent to the volume delivered.
- 6.10.11.3 If the collection volume is within the range 47.5 – 52.5 ml, the pump is properly calibrated.
- 6.10.11.4 If not, return the pump to SIGMA International, Inc. for recalibration, or perform the flow rate calibration procedure according to CTP 13000 when flow rate error is not greater than 8%.

6.11 LINE SAFETY ANALYSIS

6.11.1 Verify ground impedance is <0.13 ohms.

6.11.2 Verify chassis leakage current is <25 microamps.

6.11.3 The Line Cord is tested for chassis risk current (<15 micro amps normal, <50 microamps single fault) and safety ground resistance (<0.13 ohms) using a Line Safety Analyzer.
6.11.3.1 The AAMI Safe Currents Limits Test, SIGMA SOP 11170 (available from SIGMA International, Inc.) is the recommended test procedure.
6.11.3.2 Another procedure based on the AAMI, IEC, or CSA Line Safety tests may also be used, if so dictated by the individual safety standards of the installation site.
6.11.4 Inspect the line cord retainer to be sure that the cord can not be removed accidentally.

6.12 FLOW SENSOR OPERATION (OPTIONAL)
6.12.1 Set "RATE" to 125 and "VOL LIMIT" to 100.
6.12.1.1 Push "RUN" and allow the fluid to flow
6.12.2 Plug the appropriate tubing calibration flow sensor into the nine pin (RS – 232) connector on the rear of the pump.
6.12.3 Verify that the pump stops and displays "PUMP STOP / PUSH RUN".
6.12.4 Push "RUN" to start the pump with the flow sensor off of the set's drip chamber.
6.12.5 Verify that the pump goes into an audio alarm and displays "EMPT BOTT / CLR OCC" approximately 10 seconds after the pump started.
6.12.6 Connect the flow sensor to the set's drip chamber and push "RUN".
6.12.6.1 Allow the pump to run for >40 seconds.
6.12.7 Verify that the pump runs without an "EMPT BOTT / CLR OCC" alarm while the drops are correctly flowing.
6.12.8 While the pump is continuing to run, disconnect the flow sensor from the RS – 232 plug.
6.12.9 Verify that the pump stops and display indicates "PUMP STOP / PUSH RUN".

6.13 BATTERY CAPACITY TEST
6.13.1 The storage capacity for the battery in the Model 8000 may be determined by running the Battery Capacity Test.
6.13.2 The Model 8000 must be connected to the AC line for at least 24 hours prior to the test, to allow the battery to attain full charge.
6.13.2.1 The Model 8000 may be in use during this time.
6.13.3 Biomed Option #402 (available in 4meg pumps* V3.29.00 and later) may be used to perform automatic monitoring of the battery capacity test. See alternate method step 6.13.4 for other pump configurations.
6.13.3.1 Enter Biomed Option #402 as indicated in section 1.7 of the Service Manual.
6.13.3.2 Follow the prompts using the "ENTER" key, push the "Run" key to start the test.
6.13.3.3 Allow the pump to run until it turns itself off.
6.13.3.4 Plug the pump into AC. Turn pump on and observe resulting test times displayed.
6.13.3.5 Confirm capacity per step 6.13.6.
* Pump 4 meg and software version can be determined by accessing Biomed Option #200.
6.13.4 The following alternate method may be used, with an IV set in place, the pump is started with "RATE" of 100 ml / hr and "VOL LIMIT" of 500 ml selected to give a delivery time of 5 hours.

6.13.5 The time is noted, or timer started, and the line cord unplugged from the wall, with the pump in operation.
6.13.5.1 The pump will alarm when the battery capacity is nearly depleted ("LOW BATT"), and will turn off when the battery reaches exhaustion (following "PLUG IN").
6.13.5.2 The battery voltage at shutdown is approximately 10.4 volts.
6.13.6 Elapsed time to pump shutdown should be at least 2 hours, with a fully charged battery, that includes ≥31 minutes between "Low Batt" and "Plug In" messages (L → P Time).
6.13.6.1 Less battery capacity indicates a battery reaching end of life.
6.13.6.2 See section 1.9 of the Model 8000 Service Manual for the Battery Replacement Procedure.

6.14 BATTERY CAPACITY TEST MODEL 8002 ONLY
6.14.1 The storage capacity for the battery in the Model 8002 may be determined by running the Battery Capacity Test.

6.14.2 The Model 8002 must be connected to the AC line for at least 24 hours prior to the test, to allow the battery to attain full charge.
6.14.2.1 The pump may be in use during this time.
6.14.3 With an IV set in place, start both channels with a "RATE" of 100 ml / hr and "VOL LIMIT" of 500 ml selected to give a delivery time of 5 hours.
6.14.4 The time is noted, or timer started, and the line cord unplugged from the wall, with the pump in operation.
6.14.4.1 The pump will alarm when the battery capacity is nearly depleted ("LOW BATT"), and will turn off when the battery reaches exhaustion (following "PLUG IN").
6.14.4.2 The battery voltage at shutdown is approximately 10.4 volts.
6.14.5 Elapsed time to pump shutdown should be at least 1.5 hours, with a fully charged battery, that includes ≥31 minutes between "Low Batt" and "Plug In" messages (L → P Time).
6.14.5.1 Less battery capacity indicates a battery reaching end of life.
6.14.6 See section 1.9 of the Model 8000/8002 Service Manual for the Battery Replacement Procedure.

6.15 Setting PM Due Date.
6.15.1 Biomed Option #210 (available in 4meg* V3.29.00 and later) may be used to set up a PM Due display and alarm.
6.15.1.1 If the alarm is enabled (on), the display "PM DUE" and a short alarm will be given on power up of the pump once the set due date has been reached. The alarm will be given on every power up until reset or disabled (turned off)
6.15.2 To set up this feature, enter Biomed Option #210 as indicated in the Service Manual, Section 1.7.
6.15.3 Follow the prompts and use the keypad to enter the year, month and day for the next PM Due Date. Each entry must be followed by pressing the "ENTER" key.
6.15.4 Toggle the alarm setting ON or OFF using the "CLEAR/NO" key as desired. Press the "ENTER" key to save all settings and exit the option.
* Pump 4 meg and software version can be determined by accessing Biomed Option #200.

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SERIAL NUMBER: _____ DATE: _____ CHANNEL (circle one): **A B N/A**

CUSTOMER CONTROL NUMBER: _____

PREVENTATIVE MAINTENANCE CHECK OFF SHEET

6.2	VISUAL INSPECTION	PASS_____ FAIL_____
6.3	VISUAL INSPECTION FOR MODEL 8002 ONLY	PASS_____ FAIL_____
6.4	KEYBOARD TEST	PASS_____ FAIL_____
6.5	UPSTREAM (PROXIMAL) OCCLUSION SENSOR TEST	PASS_____ FAIL_____
6.6	AIR DETECTION TEST	PASS_____ FAIL_____
6.7	DOWNSTREAM (DISTAL) OCCLUSION SENSOR TEST _____PSI OR _____MM/HG	PASS_____ FAIL_____
6.8	MEMORY TEST	PASS_____ FAIL_____
6.9	LOW FLOW RATE ACCURACY TEST FOR MODEL 8002 ONLY VOLUME OUTPUT _____ML	PASS_____ FAIL_____
6.10	FLOW RATE ACCURACY TEST VOLUME OUTPUT _____ML VOLUME OUTPUT _____ML (required for SOP 35002-9 only) VOLUME OUTPUT _____ML (required for SOP 35002-9 only) VOLUME OUTPUT _____ML (required for SOP 35002-9 only)	PASS_____ FAIL_____
6.11	LINE SAFETY ANALYSIS	PASS_____ FAIL_____
6.12	FLOW SENSOR OPERATION	PASS_____ FAIL_____
6.13	BATTERY CAPACITY TEST TIME TO "PLUG IN" ALARM _____HRS.	PASS_____ FAIL_____
6.15	NEXT PM DUE DATE IF ENABLED	PM DUE DATE: _____

TESTER: _____ DATE: _____

1.6 USER ACCESSIBLE OPTIONS

1.6.1 INSTRUCTIONS FOR USER OPTIONS

A series of selectable options are available to the user for customizing pump operation. Once the options are programmed the pump will operate according to the selected options until the user again changes them. To access the options:

1. Identify the desired option code number from the following list (or the list on the side label of the pump).

2. Press the 'OPTIONS' key.

3. Select the desired option code number using the numeric keys, and then press the 'ENTER' key.

4. Operator prompts indicate the information that must be entered using the numeric keys and/or the 'ENTER' ('YES') key or the 'CLEAR' ('NO') key. When all values are properly set in the option, the pump will either indicate "PUSH RUN" for the optional operating mode just set, or will return to the previous operating mode from options which do not affect the mode of operation of the pump.

5. Once an option has been entered, to review all entries prior to starting the infusion, repeatedly press the 'ENTER' key.

6. To erase a mistaken entry press the 'CLEAR' key when the mistake displays, then enter the correct value and press the 'ENTER' key. To erase and leave an entire option mode press the 'CLEAR' key while the option code number, option name, “PUSH ENTR” or "PUSH RUN" is displaying.

7. To access additional options, before starting the pump, wait until the "PUSH RUN" displays, then repeat steps 2-4.

Opt. #	Option Name	Description of Option NA = Not Available	Pump Display
10	AUDIO ALARM DEFAULT TONE LEVEL	Select Default level for Audio alarm tone. Option will display and sound, i.e. demo, the current default. Press integer from 1 (quiet) to 3 (loud). The new choice will be displayed and demo'ed. Press the ENTER key to accept the displayed value and demo the new tone. Press Clear key to reset to system default, 2. **[SRS-0160-001]**	TONE n
11	KEY LOCK ON/OFF	Option will display current status of Key Lock. Toggle Key Lock on or off by selecting the option. Can only be (de)activated when the set is loaded and the rate and volume parameters have been entered and may only be deactivated at KVO or during air/occlusion alarms. **[SRS-0160-002]**	KEY LOCK or LOCK OFF
12	RETURN TO PRIMARY MODE	Press Enter to return to Primary Mode from any Option Mode. The Option Mode's parameter values in permanent memory will be retained. **[SRS-0160-998]**	OPT 12 PRI MODE PUSH ENTR
20	PIGGYBACK TIME/VOLUME MODE	Option will display current piggyback time value and current piggyback volume value. Press Enter to accept value and calculate the rate. Press numeric key to change value. **[SRS-0160-980]**	SET PIG TIME 0 mins SET PIG VOL VOL 0 then, PIG RATE RATE xx
21	PIGGYBACK RATE/VOLUME MODE	Option will display current piggyback rate value and current piggyback volume value. Press Enter to accept value. Press numeric key to change value. **[SRS-0160-003]**	SET PIG RATE RATE 0 SET PIG VOL VOL 0
30	PRIMARY TIME/VOLUME MODE	Set up an infusion using time, in hours and minutes, and volume. (NA)	tbd
40	DOSE MODE (UN/H) Unit / hr	Displays current dose value and infusate concentration in two values. Press ENTER to accept value. Press the numeric keys to change value. **[SRS-0160-982]**	SET DOSE DOSE 0 SET CONC 0 unit SET CONC 0 mL

Opt. #	Option Name	Description of Option NA = Not Available	Pump Display
41	DOSE MODE (UNKM) Unit kg / m	Displays current dose value, infusate concentration in two values, and patient mass. Press ENTER to accept value. Press the numeric keys to change value. **[SRS-0160-983]**	SET DOSE DOSE 0 SET CONC 0 unit SET CONC 0 mLl SET kg 0 kg
42	DOSE MODE (UNKH) Unit kg / h	Displays current dose value, infusate concentration in two values, and patient mass. Press ENTER to accept value. Press the numeric keys to change value. **[SRS-0160-984]**	SET DOSE DOSE 0 SET CONC 0 unit SET CONC 0 mL SET kg 0 kg
43	DOSE MODE (MU/M) mUnit / m	Displays current dose value and infusate concentration in two values. Press ENTER to accept value. Press the numeric keys to change value. **[SRS-0160-985]**	SET DOSE DOSE 0 SET CONC 0 unit SET CONC 0 ml
44	DOSE MODE (G/H) gram / hr	Displays current dose value and infusate concentration in two values. Press ENTER to accept value. Press the numeric keys to change value. **[SRS-0160-986]**	SET DOSE DOSE 0 SET CONC 0 g SET CONC 0 ml
50	DOSE MODE (UGKM) mcg / kg / m	Displays current dose value, infusate concentration in two values, and patient mass. Press Enter to accept value. Press numeric key to change value. **[SRS-0160-987]**	SET DOSE DOSE 0 SET CONC 0 mg SET CONC 0 ml SET kg 0 kg
51	DOSE MODE (UGKH) mcg / kg / h	Displays current dose value, infusate concentration in two values, and patient mass. Press ENTER to accept value. Press the numeric keys to change value. **[SRS-0160-988]**	SET DOSE DOSE 0 SET CONC 0 mg SET CONC 0 ml SET kg 0 kg
52	DOSE MODE (UG/M) mcg / min	Displays current dose value and infusate concentration in two values. Press ENTER to accept value. Press the numeric keys to change value. **[SRS-0160-989]**	SET DOSE DOSE 0 SET CONC 0 mg SET CONC 0 ml

Opt. #	Option Name	Description of Option NA = Not Available	Pump Display
53	DOSE MODE (UG/H) mcg / hr	Displays current dose value and infusate concentration in two values. Press ENTER to accept value. Press the numeric keys to change value. **[SRS-0160-990]**	SET DOSE DOSE 0 SET CONC 0 mg SET CONC 0 ml
54	DOSE MODE (MGKM) mg / kg / m	Displays current dose value, infusate concentration in two values, and patient mass. Press ENTER to accept value. Press the numeric keys to change value. **[SRS-0160-991]**	SET DOSE DOSE 0 SET CONC 0 mg SET CONC 0 ml SET kg 0 kg
55	DOSE MODE (MGKH) mg / kg / h	Displays current dose value, infusate concentration in two values, and patient mass. Press ENTER to accept value. Press the numeric keys to change value. **[SRS-0160-992]**	SET DOSE DOSE 0 SET CONC 0 mg SET CONC 0 ml SET kg 0 kg
56	DOSE MODE (MG/M) mg / min	Displays current dose value and infusate concentration in two values. Press ENTER to accept value. Press the numeric keys to change value. **[SRS-0160-993]**	SET DOSE DOSE 0 SET CONC 0 mg SET CONC 0 ml
57	DOSE MODE (MG/H) mg / hr	Displays current dose value and infusate concentration in two values. Press ENTER to accept value. Press the numeric keys to change value. **[SRS-0160-994]**	SET DOSE DOSE 0 SET CONC 0 mg SET CONC 0 ml
60	PROGRAM MODE – AUTOMATIC *4meg feature	Calculates a 21-step program to deliver the selected volume (VOL) over the selected time (hrs) in which the first and last ten steps are done at increasingly higher and lower rates, respectively. Beginning at 50% of the main rate, the ramp up increases at 5% per step until the main rate is reached at step 11. The ramp down is the same process in reverse. The ramp steps are each 1%, and the main infusion is 80% of the total time. **[SRS-0160-999]**	SET PROG VOL 0 SET PROG 0 hrs
61	PROGRAM MODE – IMMEDIATE RAMP DOWN *4meg feature	Allowed only when an automatic program mode, Option 60 or 62, is already set, the step number is changed to the first step of the down ramp, or taper, which is step 12 in the case of the Auto Program Mode. **[SRS-0160-995]**	AUTO TAPR or NO AUTO PROG

Opt. #	Option Name	Description of Option NA = Not Available	Pump Display
62	PROGRAM MODE – AUTOMATIC, WITH CUSTOM RAMPS *4meg feature	Calculates a 21-step program to deliver the selected volume (VOL) over the selected time (hrs) in which the ramp time (RAMP hrs) climbing to main rate and the taper time (TAPR hrs) descending from main rate can be set by the user. Beginning at 50% of the main rate, the ramp up increases at 5% per step until the main rate is reached at step 11. The taper down is the same process in reverse. The ramp steps are each 1%, and the main infusion is 80% of the total time. **[SRS-0160-981]**	SET PROG VOL 0 SET PROG 0 hrs SET RAMP RAMP UP 0 hrs SET TAPR TAPR DOWN 0 hrs
63	PROGRAM MODE – MANUAL *4meg feature	Up to eleven program steps, stored in permanent memory, are made available to the user to select whatever rates and volumes are desired. They are run as a continuous program until they are all finished. **[SRS-0160-997]**	SET RT 1 RT 1 0 SET VL 1 VL 1 0 …
64	PROGRAM MODE – MANUAL *4meg feature	This provides another set of eleven program steps, and works the same as Option 63. **[SRS-0160-996]**	SET RT 1 RT 1 0 SET VL 1 VL 1 0 …
70	SET DS OCCLUSION PRESSURE (psi)	Set pressure limit for downstream occlusion sensor in psi. CLEAR key displays default value of 10psi. Range of 2 -15 psi **[SRS-0160-005]**	OCCL nn nn psi
71	SET DS OCCLUSION PRESSURE (mm Hg)	Set pressure limit for downstream occlusion sensor in mmHg. CLEAR key displays default value of 500 mmHg. Range of 100 - 750 mmHg **[SRS-0160-980]**	OCCL nn nn mmHg
72	ENABLE DOWNSTREAM PRESSURE DISPLAY	Enables or disables the Downstream Pressure Graphic Trend display that will be included in the running display sequence. **[SRS-0160-979]**	DISP ON? DISP ON or DISP OFF
73	DISPLAY DOWNSTREAM PRESSURE GRAPHIC	Displays the downstream pressure graphic for 30 seconds, whether the pump is running or not. **[SRS-0160-978]**	> >> >>> >>>> >>>> > >>>> >> >>>> >>> >>>> >>>>
80 (8000 *Plus* ONLY)	DRUG LABEL (ENABLE / DISABLE) Software Versions – 3.5X.XX *4meg feature	Option will display current status of the Drug Label feature. Toggle Drug Label on or off by selecting the option. **[SRS-0160-300]**	LABL ON or LABL OFF

Opt. #	Option Name	Description of Option NA = Not Available	Pump Display
80 (8000 *Plus* ONLY)	DRUG LABEL (Software Versions 4.00 and higher) *4meg feature	Option allows the addition of a label if no infusion parameters are entered. (Drug Library is enabled in the Biomed Mode)	DRUG LABL YES? / NO?
81 (8000 *Plus* ONLY)	CLEAR DRUG LABELS *4meg feature	Clear any assigned drug labels and remove them from the running display. Retains the current status of the Drug Label feature. **[SRS-0160-301]**	LABL CLRD
88	FACTORY OPTIONS	Select the **Factory Option**. These options are restricted to in-house personnel only. **[SRS-0160-976]**	SET FACT OPT PASS WORD
89	BIOMED OPTIONS	Select BioMed option (see the **BioMed Options** section of this document). Press numeric keys to select option number. Press Clear key to exit mode. **[SRS-0160-006]**	SET BIO OPT and OPT nn < title > PUSH ENTR
90	DELAYED START (currently not available in software later than v3.28) *4meg feature	Enables the user to delay the start of an infusion, with or without a KVO infusion during the start delay period and after the infusion is complete. Start delay and KVO alarm delay times are entered. If no infusion mode is set up, Primary Mode is then suggested but any Alternate Mode is allowed. Once the desired mode is set up, the RUN key is pressed to begin the delayed infusion. At the end of the infusion, a KVO alarm delay will begin, if selected, after which the KVO alarm will sound. **[SRS-0160-977]**	SET DLYD STRT 0 hrs KVO ON YES NO? DLAY END KVO ALRM 0 hrs PRI MODE YES NO? SET OPT CODE DLAY STRT <mode> IN STOP PUSH RUN RATE KVO KVO ALRM x.x hrs <mode> INF COMP RATE KVO PUSH STOP
95	CLEAR ALL PROGRAM MODE VALUES	Reset all Program Mode parameters to default values. Includes all Rate, Volume, Ramp Up, Taper Down and Total Program time values. The mode of the pump will revert to Primary if this option is used while the pump is in a Program Mode **[SRS-0160-096]**	PRGS CLRD

Opt. #	Option Name	Description of Option NA = Not Available	Pump Display
99	CLEAR ALL USER VALUES	Reset all possible user-changeable variables to default values. Primary Rate, Volume and Time will be assigned their default values. Variables cleared to zero are total volume, current rate and volume, running time and vol-limit, piggyback rate, volume and time, dose mode kg, vol, mg and ugkm values, but not Program Mode variables. **[SRS-0160-007]**	ALL CLR

1.7 BIOMEDICAL ACCESSIBLE OPTIONS

1.7.1 INSTRUCTIONS FOR BIOMEDICAL OPTIONS

A series of selectable options are available to the biomedical technician for customizing certain aspects of pump operation. Once the options are programmed, the pump will operate according to the selected options until the biomedical technician changes them. They may be accessed as follows:

1. Select the 'OPTIONS' key from the main menu display sequence of the pump, "SET OPT CODE" will display. Using the numeric keys, enter '89' as the option number and press the 'ENTER' key. The display will then show "SET BIO OPT".

2. At this time an option code number for a specific option from the following list may be entered by use of the numeric keys, followed by the 'ENTER' key, to go directly to any of the listed options (*see note). If the user enters into an option in error, pressing the 'OPTIONS' key will exit the present option without change to any of the option settings.

3. Pressing the 'ENTER' key while a particular option is displayed allows the biomedical technician to make changes to the set up for that option (*see note). The option may be changed by use of the numeric keys, the 'CLEAR' key (to clear an entry error or toggle between choices), and the 'ENTER' key (to accept the currently displayed value or setting) as indicated in each of the following sections.

4. While setting an option, at any point before the final 'ENTER' key is pressed within that option, the 'OPTIONS' key may be pressed to immediately exit that option and discard all of the changes made, i.e. the settings that were in effect before entry into that option will remain unchanged.

5. Selecting 'OPT 0', then pressing the 'ENTER' key from the "SET BIO OPT" display, or any of the "OPT ###" displays, will exit the user from this menu, enable any changes made to the options, and return the pump to the user operating mode.

* **NOTE:** An access password is required to enter into certain Biomed options. Some of the options require service school certification for access. Contact SIGMA International Service Department for details.

Opt. #	Option Name	Description of Option	Pump Display
100	AIR SENSOR DISABLE	Select Air Sensor Enabled/Disabled with Flow Detector installed. Option will display Air Sensor status. Push Clear key to toggle status between On and Off. Push Enter key to accept displayed status. Push Options key to exit with no change from original status.	AIR ENA AIR ON *or* AIR OFF
110	UPSTREAM OCCLUSION SENSOR DISABLE	Select Upstream Occlusion Sensor Enabled/Disabled with Flow Detector installed. Option will display US Occl Sensor status. Push Clear key to toggle status between On and Off. Push Enter key to accept displayed status. Push Options key to exit with no change from original status.	↑OCC ENA ↑OCC ON *or* ↑OCC OFF
111	UPSTREAM OCCLUSION RUN LOCKOUT ENABLE	Protected option to enable/disable the RUN key lockout after consecutive upstream occlusions have occurred. CLEAR to toggle, ENTER to select, OPTIONS to exit with no change made. Currently supported in Hospira calibration only.	↑OCC LOCK LOCK ON *or* LOCK OFF
120	DOWNSTREAM OCCLUSION SENSOR DISABLE	Select Downstream Occlusion Sensor Enabled/Disabled. Option will display DS Occl Sensor status. Push Clear key to toggle status between On and Off. Push Enter key to accept displayed status. Push Options key to exit with no change from original status. Modification of this setting requires entry of the restricted-access password.	↓OCC ENA PASS WORD ↓OCC ON *or* ↓OCC OFF
130	ROLLER CLAMP SENSOR DISABLE	Select Roller Clamp Sensor Enabled/Disabled. (NA)	RCLP ENA OPT N/A
140	FLOW DETECTOR REQUIRED ENABLE	Set Flow Detector Required On or Off.	FLOW SNSR FDET ON *or* FDET OFF
150	DOWNSTREAM OCCLUSION AUTO-RESTART DISABLE	Select Downstream Occlusion Auto-Restart Enabled/Disabled. Option will display DS Occl Auto-Restart status. Push Clear key to toggle status between On and Off. Push Enter key to accept displayed status. Push Options key to exit with no change from original status.	DSAR ENA DSAR ON *or* DSAR OFF
151	DOWNSTREAM OCCLUSION DEFAULT PRESSURE LIMIT	Press CLEAR to enable/disable the feature. Press ENTER to accept the setting. Use the numeric keys to enter a value. Press OPTIONS to exit setup with no change.	DFLT OFF DFLT ON SET DFLT xx psi

Opt. #	Option Name	Description of Option	Pump Display
160	TEMPERATURE COMPENSATION ENABLE	General-access protection. Press CLEAR to enable/disable this feature. Press ENTER to accept the setting. Press OPTIONS to exit setup with no change.	TEMP COMP PASS WORD COMP ON COMP OFF
200	DISPLAY SOFTWARE INFORMATION	Display Software Version Number and PROM size indicator.	SOFT WARE V xx xxxx SUB xxxx 2MEG PROM 4MEG PROM
201	DISPLAY PUMP SERIAL NUMBER	Display pump Serial Number. Provides one-time access to the serial number. Once the value has been entered, this option is view-only.	PUMP SN SN 0 CON FIRM SN x xxxx PUSH ENTR *once set,* SN x xxxx
202*	CHANGE PUMP SERIAL NUMBER *4meg feature	Protected option that allows the pump serial number to be entered, corrected, or reentered in the event of memory corruption. Modification of this value requires entry of the restricted-access password. General-access password provides read-only rights.	SET SN PASS WORD SN x xxxx SN y yyyy CON FIRM SN y yyyy PUSH ENTR *once set,* SN y yyyy
210*	SET PM DUE DATE *4meg feature	Set date when Preventative Maintenance Due message will be displayed by typing in the year, month, and day values. The user is then prompted to enable or disable the notification alarm.	PM DUE YEAR xxxx MON xx DAY xx ALRM ON *or* ALRM OFF

Opt. #	Option Name	Description of Option	Pump Display
220	USER OPTIONS DISABLE/ENABLE	Allows user to disable or enable the User Options. The user is prompted initially to enable and/or disable all User Options and then given the choice to exit the mode. The user is then prompted to enable and/or disable all Dose Modes and once again given the choice to leave the mode. If the user stays in the mode, at this point he or she is prompted to enter the number of the option desired to be either disabled or enabled. The choice to exit the option is presented again and if denied, the prompt to enable or disable another option number is redisplayed. The CLEAR key toggles the response selections (YES/NO or ON/OFF), the ENTER key accepts the selection and OPTIONS exits the mode with no changes saved. If any changes are made and the pump was not in Primary Mode previous to entering this BioMed Option, PRI MODE is displayed for 2 seconds and the pump will revert to Primary upon exit of the mode.	OPT DISA ENA ALL? ALL ON DONE NOW? DISA ALL? ALL OFF DONE NOW? PRI MODE *(if settings were changed)* SET BIO OPT DOSE ON? DOSE ON DONE NOW? DOSE OFF? DOSE OFF DONE NOW? PRI MODE *(if settings were changed)* SET BIO OPT SET OPT CODE OPT nn OPT ON *or* OPT OFF DONE NOW? PRI MODE *(if settings were changed)* SET BIO OPT *or* SET OPT CODE

Opt. #	Option Name	Description of Option	Pump Display
221	TITRATION DISABLE/ENABLE	Allows user to disable or enable Titration. OPTIONS exits the option with no change. CLEAR toggles between on and off. ENTER accepts the displayed status (on or off) and exits the option.	TITR DISA TITR ON *or* TITR OFF
230	SET INITIAL POWER-ON PROMPT	Set initial prompt displayed at power-on. (NA)	tbd
231	SET SPECIAL DISPLAY OPTIONS	Allows custom setting of the Primary Total Volume, Dose Total Volume, Primary Volume, Dose Volume, and Battery Indicator running display prompts (4meg version only). Press CLEAR to toggle status between On and Off. Press ENTER to accept the value. Press OPTIONS to exit the option with no changes.	ALT DISP PRI TOTL TOTL ON *or* TOTL OFF DOSE TOTL TOTL ON *or* TOTL OFF PRI VOL VOL ON *or* VOL OFF DOSE VOL VOL ON *or* VOL OFF (4meg only) BATT DISP DISP ON *or* DISP OFF
232	DISABLE CHECK PIG CLAMP PROMPT	Option will display the “check pig clamp” prompt status. Push CLEAR to toggle, ENTER to select, OPTIONS to exit with no change from original status.	PIG CLMP ALRT ON ALRT OFF
240	RASPBERRY ALARM	Disable or enable the lever-improperly-positioned “raspberry” buzzer and/or set its default volume. Press 0 to disable it, CLEAR to set it to the medium level, 1 for low, 2 for medium, or 3 for loudest. NVRAM Init will leave it on at medium.	RASP ALRM TONE n
241	KEY BEEP DISABLE	Select Key Beep Enabled/Disabled. Option will display Key Beep status. Push CLEAR key to toggle status between On and Off. Push ENTER key to accept displayed status. Push OPTIONS key to exit with no change from original status.	KYBP ENA KYBP ON *or* KYBP OFF
242	PIGGYBACK COMPLETE BEEP ENABLE	Enable/disable the four beeps sounded at Piggyback infusion complete (default is disabled).	BEEP OFF *or* BEEP ON
250	INACTIVITY TIMEOUT ALARM DELAY	Set the alarm timer at 2 or 5 minutes. OPTIONS will exit the mode with no change, CLEAR will toggle between 2 and 5 minutes, ENTER sets the displayed value and exits the option.	ALRM DLAY DLAY 2MIN *or* DLAY 5MIN

Opt. #	Option Name	Description of Option	Pump Display
260*	FOREIGN LANGUAGE DISPLAY * 4meg feature	Protected option to set the language used in all pump displays to be either English or French, default to English, CLEAR to toggle, ENTER to select, selected language updated as option is exited. Modification of this value requires entry of the restricted-access password. General-access password provides read-only rights.	LANG UAGE PASS WORD ENGL ISH YES? NO? FRAN CAIS OUI? NON?
270	ENABLE HP/CAREVUE OUTPUT	Either enable or disable the serial output of data relevant to the Hewlett-Packard Device Link/CareVue system. CLEAR to toggle, ENTER to select. General-access password required.	CARE VUE PASS WORD SYS ON SYS OFF
280*	CLEAR HISTORY COUNTERS * 4meg feature	Allows the cumulative totals stored in EEPROM to be cleared when needed. For example, when the battery pack is replaced, the user may clear from memory the total time that the pump ran on the old battery and reset it to zero for the new battery. The user may select to either clear a specific value or all the values at once indicated in the column to the right. Once a choice has been made, the user must confirm the intent to clear as the value is not recoverable once it has been zeroed.	CLR TOTS PASS WORD CLR ALL *or* BATT TOTL *or* REV TOTL *or* RUN TOTL *or* POWR TOTL *or* LEV TOTL *or* CLMP TOTL *shown with* YES? NO? CON FIRM <choice> CLEA RING
291*	DOSE MODE TEXT ABBREVIATION * 4meg feature	Allows the user to select between showing dose mode displays in abbreviated or unabbreviated form. Press CLEAR to toggle selection, press ENTER to select, press OPTIONS to exit with no change. Selection is stored in permanent memory.	DOSE ABBR ABBR OFF *or* ABBR ON

Opt. #	Option Name	Description of Option	Pump Display
300	SET MAXIMUM RATE VALUE	Set maximum allowed value to be entered for primary Rate. Enter the new value using the numeric and decimal keys. Press CLEAR to reset to default value of 999. Press OPTIONS to exit the option with no change to the old value. Press ENTER to accept the new value.	MAX RATE RATE xx *(curr value)* RATE yy *(new value)*
301	SET MAXIMUM VOLUME VALUE	Set maximum allowed value to be entered for primary Volume. Enter the new value using the numeric and decimal keys. Press CLEAR to reset to default value of 9999. Press OPTIONS to exit the option with no change to the old value. Press ENTER to accept the new value.	MAX VOL VOL xx *(curr value)* VOL yy *(new value)*
302	SET MAXIMUM TIME VALUE	Set maximum allowed value to be entered for primary Time. (NA)	tbd
303	SET MINIMUM RATE VALUE	Set minimum allowed value to be entered for primary Rate. Enter the new value using the numeric and decimal keys. Press CLEAR to reset to default value of 0. Press OPTIONS to exit the option with no change to the old value. Press ENTER to accept the new values.	MIN RATE RATE xx *(curr value)* RATE yy *(new value)*
310	SET MAXIMUM PIGGYBACK RATE VALUE	Set maximum allowed value to be entered for piggyback Rate. (NA)	tbd
311	SET MAXIMUM PIGGYBACK VOLUME VALUE	Set maximum allowed value to be entered for piggyback Volume. (NA)	tbd
312	SET MAXIMUM PIGGYBACK TIME VALUE	Set maximum allowed value to be entered for piggyback Time. (NA)	tbd
400	ENTER TEST MODE	Enter Test Mode for running pump to test it. Press Run key to start pump at rate = 100, volume = 9999; press Run key again to stop pump; press Options key to exit option and stop the pump if running. General-access password required.	TEST MODE PUSH RUN PASS WORD *(while stopped)* TEST MODE RATE 100 *(while running, with scrolling rate)*

Opt. #	Option Name	Description of Option	Pump Display
401	SENSOR TEST MODE	Sensor Test Mode for testing upstream and downstream sensors. Press CLEAR key to toggle sensor configuration; press ENTER key to accept sensor configuration; press OPTIONS key to exit the option and ignore configuration changes. Then press ENTER key to take a reading, or OPTIONS key to exit the option.	SENS TEST ↑SNS ON *or* ↑SNS OFF ↓SNS ON *or* ↓SNS OFF PUSH ENTR FOR RDNG ↑UP xxx ↑LO xxx ↓SNS xxx
402*	BATTERY TEST MODE *4meg feature	Test the life of the internal battery pack by running the pump at a rate of 100 ml/h until the battery is depleted and the pump turns itself off. All battery alarms are silenced during the test. The pump will record the time of occurrence of the low battery and plug in alarms, then turn itself off. Upon power up, the software calculates the total running time and the Low Batt-to-Plug In time and displays them to the operator in hours and minutes. General-access password required.	BATT TEST PUSH ENTR PASS WORD BATT TEST TOTL TIME *xx*hr *xx*mn PUSH ENTR L->P TIME xx mins PUSH ENTR UN PLUG PUMP BATT LOW NO TEST or BATT TEST PUSH RUN BATT TEST RATE 100 E... ./.F POWR OFF

Opt. #	Option Name	Description of Option	Pump Display
404*	DECAY TEST MODE *4meg feature	Allows the tester to run the decay test without having to type in running parameters; the rate and volume values for each test already preprogrammed by the pump software. Press RUN to start. Pump runs the "long-term" infusion, then the 32-ml sample, prompting user to continue after each iteration. The tubeset must be loaded prior to entering this option.	DCAY TEST PASS WORD IN PROC DCAY SMPL IN PROC CONT INUE YES? NO? *if set not loaded* EXIT BIO TO LOAD SET
405*	TEST FLOW MODE *4meg feature	A utility for the QA In-Process Volume Accuracy test. The parameters for each infusion are preprogrammed, or "canned" by the software. Pump stops after each volume has been delivered, press RUN to begin the next infusion. When all infusions have been run, software will prompt the tester to indicate the status of the test results. The tubeset must be loaded prior to entering this option.	TEST FLOW PASS WORD WARM UP TEST #1 TEST #2 TEST #3 TEST #4 TEST #5 *while running* FLOW TEST IN PROC ALL PASS YES? NO? CON FIRM ALL PASS *or* TEST FAIL *if set not loaded* EXIT BIO TO LOAD SET

Opt. #	Option Name	Description of Option	Pump Display
410	REINITIALIZE NVRAM	Reinitializes NVRAM to default values, updates checksum and then powers down the pump. Press Yes key to perform action, or press No or Options key to exit with no action taken.	INIT NVRM *if YES pressed:* NVRM INIT POWR OFF
420	DUMP HISTORY LOG	Dump contents of History Log out the serial port. Dump current values of history counters out the serial port.	DUMP HIST *(blinking while in progress)* DUMP DONE
421	DUMP SHORT HISTORY LOG	Dump Pump ID, History Counters and System Timestamp readings out the serial port.	SHRT HIST DUMP DONE
430	CLEAR FIX CODE	Clear an existing fix code and then power down the pump.	CLR FIX FIX 00 POWR OFF
440	TEST FUNCTION	Perform a series of tests of the pump hardware. The display will indicate if the Drop Sensor is installed or not, and will show the current drop count. The count can be cleared by pushing the Clear key. Push the Enter key to continue to the next test, or the Options key to exit the Option. The next test will display the status of four input port bits: s=syringe installed, p=pca input, l=pca lock, and i=spare i/o #1. The Enter key continues to the next test and the Options key exits the option. The last test is a thermistor reading. The Enter or Options keys exit the option.	TEST HW FLOW SNSR IN xxxx *or* OUT xxxx INPT STAT SPLI spli TEMP RDNG TEMP xxxx

Opt. #	Option Name	Description of Option	Pump Display
450	SELECT SERIAL OUTPUT	Select the source of serial output data. The first choice is between System Messages or Sensor Readings. Push the Clear key to toggle between choices, the Enter key to accept a choice, or the Options key to exit with no changes. If Sys Msgs is chosen, all sensor reading output is disabled, and the option exits. If Read Snsr is chosen, five sensor choices are presented in sequence: Upstream sensor, Downstream sensor, Power Supply voltages, Thermistor readings, and Index mark. Use Enter, Clear and Options keys as described above.	SER OUT SYS MSGS *or* READ SNSR ↑SNS ON *or* ↑SNS OFF *if ON:* FULL MSG *or* PART MSG *if FULL:* AIR MSG *or* OCCL MSG ↓SNS ON *or* ↓SNS OFF PWR ON *or* PWR OFF TEMP ON *or* TEMP OFF INDX ON *or* INDX OFF
451	SET SERIAL PARAMETERS	Set the serial communications parameters. The first choice is to set the Baud Rate. Push the Clear key to sequence through the available choices, the Enter key to accept a choice, or the Options key to exit with no changes. The second choice is to set the Character Size, and the final choice is to set the Parity. Use Enter, Clear and Options keys as described above.	SER PARM 19K2 BAUD *or* 9600 BAUD *or* 4800 BAUD *or* 2400 BAUD 7BIT CHAR *or* 8BIT CHAR NO PAR *or* ODD PAR *or* EVEN PAR
460	CALIBRATION MODE	tbd	CAL MODE
470	COMMUNICATIONS TEST MODE	Assembles a test message and employs an external loopback adapter to transmit it and read it back in.	COMM TEST TEST PASS TEST FAIL

Opt. #	Option Name	Description of Option	Pump Display
480*	DUMP PUMP CALIBRATION DATA *4meg feature	Sends all calibration values considered to be critical out the serial port where the maybe captured to a file and/or printed. Included in the list of values is pump serial number, tube type, the five motor calibration values, all upstream sensor values, the downstream notube and scale factor values, and the low and dead battery values.	DUMP DATA DUMP DONE *Sent to terminal* SN XXXX TUBE X 10 XX 40 XX 100 XX 400 XX 800 XX UFRQ XXX LFRQ XXX QDEL XX NDEL XX DRIV X UQRF XXX UNRF XXX LQRF XXX LNRF XXX UTRP XXX LTRP XXX DSNT XX DSSF XX 11.5 XXX 10.4 XXX
500	VIEW COMPENSATION DATA *(detail to the right applies to 2meg version, the 4meg version is view-only)*	Displays calibration tube information and pump motor speed calibration values. The left half of the display shows the rate, and the right half displays the calibration value. The Decimal Point key is used to enter a negative value. All values are percents, in the form xx % in the range –140 to 140. Modification of these values requires a 2meg PROM and the restricted-access password. General-access password and/or a 4meg PROM provides read-only rights.	COMP DATA PASS WORD *<tube ID>* 10 xx 40 xx 100 xx 400 xx 800 xx

Opt. #	Option Name	Description of Option	Pump Display
501*	FLOW CALIBRATION *4meg feature	Steps the user through the process of running a series of "canned" infusions, then prompts the user to type the delivered volume results of these infusions into the pump. Using these values, the software then calculates the proper amount of compensation to apply to the motor curve to ensure accurate fluid deliveries.	FLOW CAL PASS WORD WARM UP *when selected,* DCAY SMPL TEST #1 TEST #2 TEST #3 TEST #4 *while running* FLOW CAL *or* DCAY SMPL IN PROC PUSH ENTR ENTR VOLS CON FIRM COMP DATA *values are shown* STOR ING *if set not loaded* EXIT BIO TO LOAD SET

Opt. #	Option Name	Description of Option	Pump Display
502*	COMPENSATION HISTORY *4meg feature	Provides a visual record of the calibration history of the pump. Maintains the compensation factors of the five most-recent calibration attempts and posts a date stamp at the top of each. Upon entry, the run number of the most recent calibration is displayed with the date on which it was performed. Press CLEAR to scroll to the previous entry. Press ENTER to view each compensation factor of the calibration number in view.	CAL HIST CAL #n mm/d d/yy *if ENTER pressed, the comp values are displayed as shown in BioMed Option 500.*
503*	FLOW CALIBRATION PREPARATION MODE (The "4-hour break-in") *4meg feature	Runs the pump at a controlled rate for a 4-hour period to "break-in" the pressure plate and pumping assembly/mechanism in preparation for flow rate calibration. Pump automatically titrates to 100 ml/hr after the four hours have expired.	CAL PREP PASS WORD RATE 400 CAL PREP *when the 4-hour infusion completes,* RATE 100 PREP DONE
510	SET REAL TIME CLOCK	Set internal real-time clock time and date. The values displayed are the current settings. Modification of these values requires the restricted-access password. General-access password provides read-only rights.	SET CLK PASS WORD YEAR xxxx MON xx DAY xx HOUR xx MIN xx CLK SET
520	SET TUBE TYPE	Set tube type to select motor compensation table. CLEAR key clears the value to zero, ENTER key accepts value and OPTIONS exits the BMO with no changes. Entering a value greater than 9 displays VALU HIGH. Modification of these values requires the restricted-access password. General-access password provides read-only rights.	TUBE TYPE PASS WORD TUBE xx VALU HIGH
521	SET KEYPAD TYPE	Set the keypad type to select key mapping. There are three: 0 for Original Standard keypad; 1 for Revised Standard keypad with the load key shifted over, and 2 for the Braun keypad (using the calculator style layout rather than the telephone style). Entering a value greater than 9 displays VALU HIGH.	KYPD TYPE KYPD x VALU HIGH

Opt. #	Option Name	Description of Option	Pump Display
530	VIEW UPSTREAM SENSOR CALIBRATION DATA	View the upstream sensor calibration values - upper and lower transducer frequencies, quadrature and normal delay values, transducer drive level, upper and lower transducer quad and normal reference values, upper and lower transducer air trip points. Modification of these values requires the restricted-access password. General-access password provides read-only rights.	US CAL PASS WORD UFRQ xxxx LFRQ xxxx QDEL xxxx NDEL xxxx UDRV x LDRV x UQRF xxxx UNRF xxxx LQRF xxxx LNRF xxxx UTRP xxxx LTRP xxxx
531*	CALIBRATE UPSTREAM SENSOR *4meg feature	Calibrate the upstream sensor – tester is initially prompted to use default calibration values or the current values stored, then the tester is prompted to load and remove a water-filled tube and an air-filled tube. Success places the tester in BMO 530 to view the calibration results, failure will display a descriptive reason for the failure. General-access password required.	↑SNS CAL PASS WORD DFLT VALU YES? NO? WORK ING RMVE TUBE WATR TUBE AIR TUBE ↑CAL DONE BAD SNSR LOW RDNG HIGH RDNG HILO RDNG BAD REFS WIDE REFS WIDE DRIV
540	ENTER DOWNSTREAM SENSOR CALIBRATION DATA	Enter Downstream sensor calibration values – default no tube threshold value and scale factor value. General-access password required.	DS CAL PASS WORD DSNT xxxx DSSF xxxx

Opt. #	Option Name	Description of Option	Pump Display
541	CALIBRATE DOWNSTREAM SENSOR	Calibrate the Downstream sensor Scale Factor (ADC counts per PSI). Requires that a tube be already loaded into the pump, and can be pressurized to 2 psi and 18 psi. The pump takes sensor readings at the 2 psi and 18 psi pressures, displays the readings, and calculates and displays the Scale Factor. General-access password required.	DS CAL PASS WORD SET PRES TO 2PSI PUSH ENTR 2PSI xxxx SET PRES TO 1 8PSI PUSH ENTR 18P xxxx DSSF xxxx
542	CALIBRATE DOWNSTREAM NO TUBE VALUE	Calibrate the Downstream sensor No Tube value. Requires that no tube be loaded into the pump. A reading of the sensor is taken, displayed and saved. General-access password required.	DSNT CAL PASS WORD NO TUBE PUSH ENTR DSNT xxxx
550	ENTER MOTOR INDEX OFFSET VALUE	Enter index offset in value of degrees. Press CLEAR to revert to default value of 0. Press ENTER to accept the value (0 – 359 inclusive). An out-of-range value will result in a “VALU HIGH” display, then revert to the “NDX+ xxx” prompt where xxx is the previous value. Press OPTIONS to exit the option with no changes. Modification of this value requires the restricted-access password. General-access password provides read-only rights.	INDX OFST PASS WORD NDX+ xxx VALU HIGH
560	ENTER BATTERY CALIBRATION VALUES	Enter calibration values for low battery and dead battery. General-access password required.	BATT CAL PASS WORD LBAT XXXX DBAT XXXX

Opt. #	Option Name	Description of Option	Pump Display
561	CALIBRATE BATTERY THRESHOLDS	Calibrate the battery thresholds for low battery and dead battery. Requires an adjustable power supply connected to the battery terminals. General-access password required.	BATT CAL PASS WORD SET BATT TO LBAT PUSH ENTR LBAT XXXX SET BATT TO DBAT PUSH ENTR DBAT XXXX
562	DISPLAY BATTERY LEVEL IN VDC	Displays the current voltage level of the battery in Vdc. Motor may be operated to check battery under typical load conditions. General-access password required.	xx.x Vdc *(flashing when motor is in operation)*
570	DISPLAY THERMISTOR TEMPERATURE VALUE	Displays the current temperature as it reads on the thermistor located in the upstream air/occlusion sensor. CLEAR toggles between Fahrenheit and Celsius scales.	TEMP xx°F TEMP xx°C
571	CALIBRATE THERMISTOR	tbd	OPT N/A
600*	DRUG LABEL (ENABLE/DISABLE) *4meg feature *Plus* model feature Software Version 4.00 or later	Password-protected option will display current status of the Drug Error Prevention feature. Toggle the feature on or off by pressing the CLEAR/NO key, press ENTER to select the displayed status, press OPTIONS to exit with no change. Default status is enabled.	DRUG LABL PASS WORD LABL ENA Or LABL DIS

Opt. #	Option Name	Description of Option	Pump Display
601*	DRUG LIBRARY TRANSMIT *4meg feature *Plus* model feature Software version 4.00 and later	Password-protected option will transmit the contents of the stored drug library in one *Plus* model pump to another *Plus* model pump using the RS-232 port and the SIGMA "pump-to-pump" serial cable. Pump shall attempt to establish a communications link with the receiving pump. Once the transmission has completed, the pump shall prompt the technician to repeat the process, if desired.	DRUG XMIT PASS WORD WAIT ING *(blinking)* LINK ING NO LINK *(blinking while in progress)* SEND ING XMIT DONE ANOTHER YES? NO?
602*	DRUG LIBRARY RECEIVE *4meg feature *Plus* model feature Software version 4.00 and later	Password-protected option will receive the contents of a drug library being transmitted. Pump shall attempt to establish a communications link with the transmitting pump. Once the library has been successfully received, the option is exited. If the transmission fails, the default drug library is restored (see INITIALIZE DRUG LIBRARY below).	DRUG RECV PASS WORD PUSH ENTR WHEN RDY *(blinking)* LINK ING NO LINK *(blinking while in progress)* RECV ING XMIT DONE *(if transmission fails)* BAD XFER LIBR INIT *(if transmission broken)* NO LINK LIBR INIT

Opt. #	Option Name	Description of Option	Pump Display
603*	DRUG LIBRARY DUMP *4meg feature *Plus* model feature Software version 4.00 and later	Send the contents of the stored drug library along with the host pump serial number, installed software version, current drug library revision number and date of configuration, out the RS-232 port in a format suitable for viewing and storing on a PC.	DUMP LIBR *(blinking while in progress)* SEND ING DUMP DONE PUSH ENTR
604*	DRUG LIBRARY INFORMATION *4meg feature *Plus* model feature Software version 4.00 and later	Displays the current revision of the drug library along with the number of drugs in the library and the number of vacancies.	LIBR INFO v xx .yyy LIBR SIZE USED xxx FREE yyy
610*	DELETE DRUGS FROM DRUG LIBRARY *4meg feature *Plus* model feature Software version 4.00 and later	Password-protected option will allow operator to delete individual drugs from the drug library or delete all drugs at once. All actions must be confirmed. The default drug library is not affected.	DLET DRUG PASS WORD DLET ALL? YES? NO? drug name YES? OR ▼ DE LETE drug name YES? NO? DELE TED

Opt. #	Option Name	Description of Option	Pump Display
611*	ADD DRUGS TO DRUG LIBRARY *4meg feature *Plus* model feature Software version 4.00 and later	Password-protected option to allow the operator to add drugs to the drug library. Character entry is provided to spell the drug. Drug Error Prevention limits may be entered for the new drug from within this option (see BMO 612).	ADD DRUG PASS WORD ENTR DRUG _ N_ New Drug ADD LMIT YES? NO? *(if YES, see BMO 612)* ADD DRUG YES? NO?

Opt. #	Option Name	Description of Option	Pump Display
612*	ASSIGN LIMITS TO DRUGS *4meg feature *Plus* model feature Software version 4.00 and later	Password-protected option to allow the operator to assign dose rate and drug concentration limits as well as desired delivery mode to any drug in the drug library. Limits may be entered as either "soft" limits or "hard" limits, or both. *mode* is represented by the delivery mode selected to deliver the drug in units of drug over a period of time, considering patient weight when applicable. Concentration values shall be entered based on the unit type of drug per mL of diluent. If RATE mL/h is selected, operator may assign only minimum and maximum rate values – no concentration value is allowed.	DRUG LMIT PASS WORD drug name YES? OR ▼ SET MODE DOSE *mode* or RATE mL/h *(if DOSE mode selected above)* SET CONC 0 *nn*mL (nn = drug unit) sMAX DOSE 0 *mode* sMIN DOSE 0 *mode* hMAX DOSE 0 *mode* hMIN DOSE 0 *mode* *(if RATE mL/h selected above)* sMAX RATE 0 mL/h sMIN RATE 0 mL/h hMAX RATE 0 mL/h hMIN RATE 0 mL/h ANO THER YES? NO?

Opt. #	Option Name	Description of Option	Pump Display
613*	INITIALIZE DRUG LIBRARY *4meg feature *Plus* model feature Software version 4.00 and later	Password-protected option to allow the operator to initialize the drug library, restoring it to the default library shipped from the factory.	INIT LIBR PASS WORD CON FIRM LIBR INIT YES? NO? INIT DONE

1.0 PURPOSE

This procedure is an outline to verify that the batteries will provide the required capacity when used in the **SIGMA International** Model 8000 or Model 8002 Infusion pump.

2.0 SCOPE

This procedure is to ensure that the battery back-up system in all **SIGMA International** Model 8000 and model 8002 I.V. pumps will meet the specifications for new and used batteries to maintain proper operation of the pump when ac power is disconnected.

3.0 REFERENCES

ICL 35001 – Production ICL -8000

4.0 DEFINITIONS

4.1 New Battery – From the stock room to 29 days after the sale and shipment of the unit.
4.2 Used Battery – 30 days or greater after the sale and shipment of the unit.

5.0 PROCEDURE

NOTES:

- Prior to this evaluation the 2.5 Ah batteries must be charged for a minimum of 18 hours.
- Prior to this evaluation the 3.2 Ah (model 8000) or 4.5Ah (model 8002) batteries must be charged for a minimum of 24 hours.
- If the 2.5 Ah batteries had been previously in plug in, they must be charged for a minimum of 24 hours.
- Pump must remain plugged into the AC receptacle after completion of the battery test for a minimum of 18 hours.

6.14 **V3.28 and earlier or V3.29 and later, 2 MEG**

6.14.1 Verify that AC power is at the pump by the AC indicator <u>being</u> illuminated.
6.14.2 Turn the pump on.
6.14.3 Set the pump's rate to 100 ml/hr and volume for a minimum of 900 ml.
6.14.4 Unplug the pump's AC power cord from the supply.
6.14.5 Verify that the AC indicator <u>is not</u> illuminated.
6.14.6 Press RUN when prompted.
6.14.7 While the pump is running the "BATT ON" message shall be added to the display scroll sequence.
6.14.8 Verify that the time elapsed to "BATT LOW" and "PLUG IN" has met the Acceptance Criteria.
6.14.9 Document proper test completion on ICL 35001, Battery Test line, by initials and date.

6.15 **V3.29 and later, 4 MEG only**

6.15.1 Verify that AC power is at the pump by the AC indicator <u>being</u> illuminated.
6.15.2 Turn the pump on.
6.15.3 Unplug the pump's AC power cord from the supply.
6.15.4 Verify that the AC indicator <u>is not</u> illuminated.
6.15.5 Enter BMO 402 and press RUN when prompted. When testing the 8002 enter BIO 402 and press RUN on both channels simultaneously.

6.15.6 While the pump is running any numeric key may be pressed to display the battery strength gauge in the display.
6.15.7 Pump powers itself off at test completion.
6.15.8 Power the pump back on to view test results.
6.15.9 Verify that the displayed times meet the Acceptance Criteria.
6.15.10 Document proper test completion on ICL 35001, Battery Test line, by initials and date

6.0 ACCEPTANCE CRITERIA

NOTE: All restock units are to be tested at the 'new battery' criteria

6.16 **V3.28 and earlier or V3.29 and later, 2 MEG**

6.16.1 New Battery – verify > 5 hours to the "PLUG IN" message.
6.16.2 Used Battery – verify > 2 hours to the "PLUG IN" message.
6.16.3 New or Used Battery – verify $\geq$ 31 minutes from the start of "BATT LOW" to start of "PLUG IN" message.

6.17 **V3.29 and later, 4 MEG only**

6.17.1 New Battery – verify > 5 hours for "BATT TEST / TOTL TIME".
6.17.2 Used Battery – verify > 2 hours for "BATT TEST / TOTL TIME".
6.17.3 New or Used Battery – verify $\geq$ 31 minutes for "L$\rightarrow$P TIME".

6.18 **Model 8002 only**

6.18.1 New Battery – verify > 3.0 hours for "BATT TEST / TOTL TIME".
6.18.2 Used Battery – verify > 1.5 hours for "BATT TEST / TOTL TIME".
6.18.3 New or Used Battery – verify $\geq$ 31 minutes for "L$\rightarrow$P TIME".

1.8 TROUBLE SHOOTING GUIDE

A comprehensive Trouble Shooting Guide is planned for the Model 8000. Following is a description of internally generated codes used to define failures.

1.8.1 SIGMA MODEL 8000 "FIX ME" CODE DESCRIPTIONS

A series of error codes are generated by the software of the SIGMA 8000 Infusion Pump, then displayed on the pump. The following error codes, or "FIX ME" codes, are intended to help the biomedical engineer to identify problems encountered during operation of the pump for assistance in repair of the product.

FIX CODE#	DESCRIPTION OF PROBLEM ENCOUNTERED
FIX 01	Software has detected a failure of the microprocessor during the self test. (CPU)
FIX 02	Software has detected a failure of the PROM checksum during the system PROM test. (PRM)
FIX 03	Software has detected a failure of the RAM during the read/write system RAM test. (RAM)
FIX 04*	Software has detected a failure of the non- volatile RAM during the system RAM test.(NVRAM)
FIX 05**	Software has detected a failure of the EEPROM checksum during the system EEPROM test. (EEPRF)
FIX 06	Software has detected a failure of the EEPROM checksum during the system EEPROM test. (EEPRV)
FIX 07	Software has detected a failure of the Real Time Clock during the system clock test. (RTC)
FIX 08	Software has detected a failure of the external clock in the system. (CLK)
FIX 14	Software has detected a data integrity failure while sorting the Drug Library. The library will have to be copied back into this pump (see Biomed Option 601 and 602).
FIX 15	Software has detected a failure of the drug library check value during the diagnostic of this memory space. (Factory default drug library is restored once this alarm is cleard.)
FIX 17	The Index mark was never detected while the pump was running. (INDEX)
FIX 18	The processor is running in limp mode - system clock failure. (LIMP)
FIX 19	The software has detected that the upstream sensor has failed. (USSENSOR)
FIX 21	The Downstream Sensor is returning a “no tube” value beyond the acceptable level.
FIX 22	The battery charge circuit has failed.
FIX 23	Lever is not detected in closed position.
FIX 24***	User has improperly unloaded the set (lever has remained closed).
FIX 69	Illegal rate value detected at motor start.
FIX 97	Software detected that a timer was illegally in use. (TIMERERR)
FIX 98	Software has detected that a timer allocation has failed (ALLOCFAIL)

Fix codes can be cleared by using the following method (V3.28 and earlier)**:**

- Select BioMed options by pressing the OPTIONS key followed by 89 and the ENTER key.
- Select BioMed option 430 by pressing 430 followed by the ENTER key.
- Exit out of the BioMed options by pressing 0 followed by the ENTER key.
- Turn the pump off then on by pressing the ON/OFF key.
- If the FIX code has been cleared the pump can be returned for use.

Fix codes can be cleared by using the following method (V3.29 and later)**:**

- Select BioMed options by pressing the OPTION key followed by 89 and the ENTER key.
- Select BioMed option 430 by pressing 430 followed by the ENTER key.
- The pump will turn off at this point.
- Previous versions of software (prior to V3.29) require that the “ON/OFF” key be pressed to turn off the pump at this time.

(*) - When a FIX 04 message occurs, enter Biomed Option 160 and confirm that the temperature compensation is properly configured for the pump. The thermistor used for temperature compensation is located in the upstream sensor area of the tube channel and can be identified as a green block in the center rib on the left side of the sensor.

- Ensure that COMP ON is set in Biomed Option 160 if the thermistor is present.
- Ensure that COMP OFF is set in Biomed Option 160 if the thermistor is not present.

If your facility is using the 'Carevue' monitoring system, ensure that the feature is enabled in Biomed Option 270. Also, if your facility is not using the Drug Error Prevention feature, you must disable it in Biomed Option 600.

(**) - When a FIX 05 message occurs the pump must be returned to the factory for service due to the possible corruption of calibration data.

(***) - When a FIX 24 message occurs it is essential that the pumping channel is carefully inspected to ensure that a fragment of tubing is not present. Turn the pump on and load a closed roller clamp to unlock the lever, open the lever fully and inspect the pumping channel.

1.9.1 RETURN AUTHORIZATION

Contact SIGMA International, LLC for all service information at:

Telephone: 1-800-356-3454, or 585-798-3901
Or write: SIGMA International, Inc.
711 Park Avenue
Medina, N.Y. 14103

Email Service Coordinator at: jallport@sigmapumps.com

Please be prepared to provide the serial number and a description of the difficulty experienced (including all pertinent information such as flow rate, administration set used, and the message displayed at the time of the difficulty).

Important: Confirm pump failure as described in this manual before return. Unconfirmed complaints are required to go through Production Testing and Quality Assurance Inspection and will be billed accordingly (See Warranty).

If it is necessary to return the unit for service:

1. Contact the SIGMA International service center above for authorization (RA) number.
2. A purchase order number or other authorized form of payment will be required on non-warranty repairs before a RA number is issued.
3. If an estimate is required before work is performed, state this when you call in for a RA number.
4. Clearly reference on all applicable documents:
    a. RA number.
    b. Purchase order number.
    c. Written description of problem.
    d. Name, telephone number, e-mail and mailing address of the following people in your hospital or organization.
        - Repair Service Manager
        - Purchasing Manager
        - Accounts Payable Manager

        (Please note that the above information is required for both the independent biomedical service company and for the pump owner, in cases where SIGMA is not dealing directly with the pump owner.)
    e. Complete name and address.
5. Package pump in the original shipping container (replacement available upon request) and affix the RA number on the outside of the package.
6. Ship pump, freight prepaid, by traceable means to: SIGMA International, LLC.
7. When a device is warranted or under a service agreement, it is returned freight prepaid.

8. SIGMA International, Inc. will not be responsible for unauthorized returns or units damaged in shipment due to improper packing.

1.9.2 FIELD SERVICE

Authorization: Verbal authorization must be obtained in advance, before field service can be performed. Written documentation will also be required.

Parts: While under warranty, SIGMA will supply factory trained/authorized service technicians with no charge parts as needed. All defective warranty parts must be returned to SIGMA.

1.9.3 BATTERY REMOVAL AND REPLACEMENT

Should removal of the battery become necessary for any reason, the following procedure may be used. Refer to Figure 1.9.4, on the next page, for the location of parts. Defective batteries should be returned to a local battery-recycling center, or to SIGMA International, for recycling.

DO NOT dispose of sealed lead batteries in the garbage.
DO NOT short circuit or drop a battery.

CAUTION - Spilled sulfuric acid from a broken battery case must be neutralized with baking soda, household ammonia or a commercially available chemical spill kit, and rinsed away with water. Skin or eyes contacted by sulfuric acid must be flushed with large amounts of water, and receive immediate medical attention, to prevent serious burns or blindness.

1. Disconnect the Line Cord, and lay the Model 8000 Pump on its front. Use a protective surface, such as plastic foam, to prevent damage to the front panel.

2. Loosen the four screws securing the pole clamp assembly and lift the assembly away from the case.

3. Disconnect 6P2, the battery connector, and lay the pole clamp over the side of the pump.

4. Note the positions of any anti-rattle pads around the batteries, and remove them if necessary. The batteries may now be lifted out. On newer pumps the foam pads will be attached to the case and will not be on the batteries.

5. Position new batteries in the battery compartment, and replace the pads (replace pads to case if not on replacement batteries), 6P2, and pole clamp in their original positions. Allow the new battery to charge for 18 - 24 hours, with the Pump plugged in.

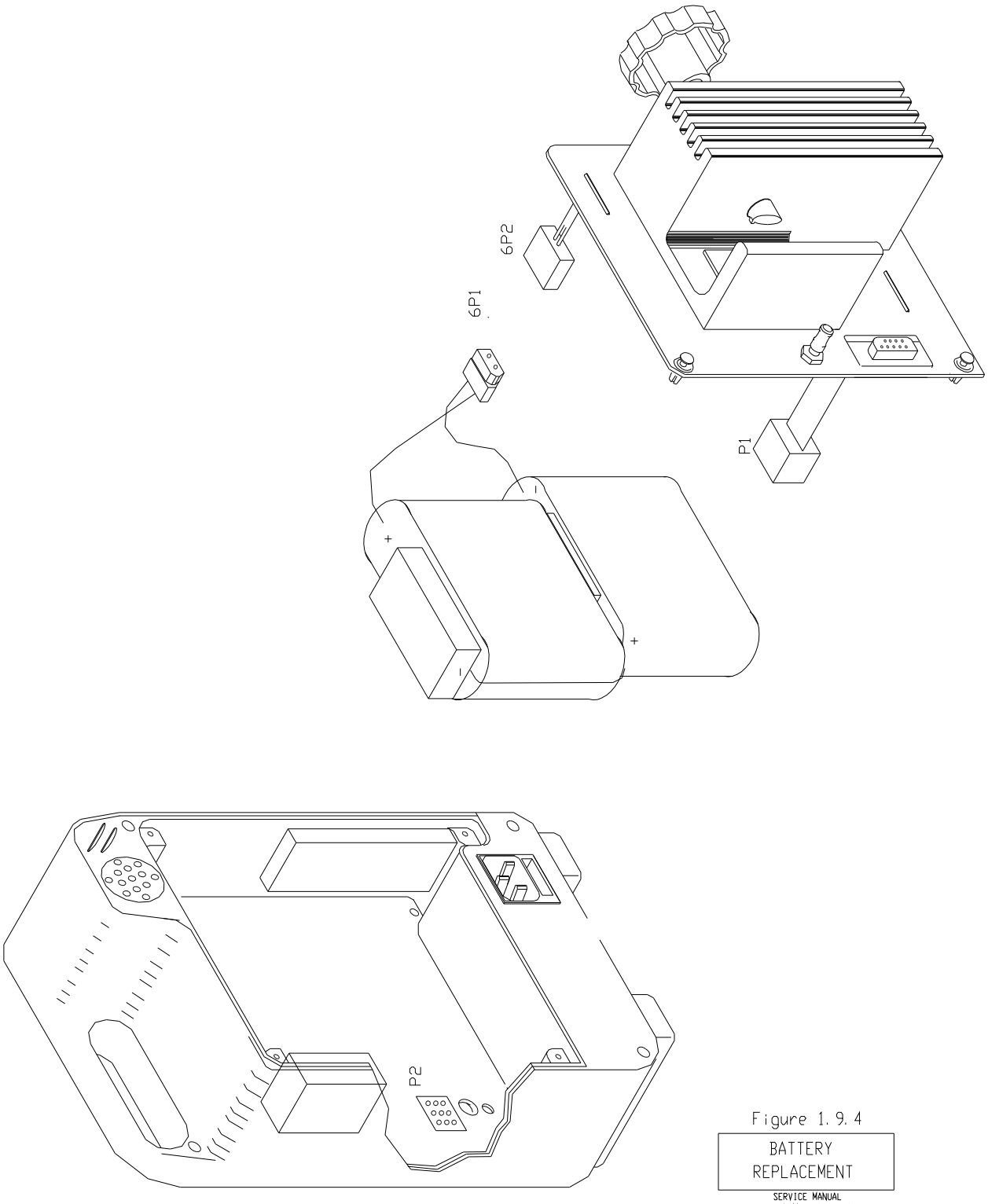


Figure 1.9.4

BATTERY REPLACEMENT

SERVICE MANUAL
FILE NAME: BATTRPLA.DWG

1.0 PURPOSE

1.1 The purpose of this procedure is to provide the necessary steps for field PROM upgrades and to provide the manufacturer a tool for upgrading the Device History File and Tracking Database.

2.0 SCOPE

2.1 This procedure applies to all SIGMA Model 8000 units.

3.0 REFERENCES

3.1 SOP 11088 - PROM Installation Procedure – SIGMA Model 8000 Infusion Pump.
3.2 SOP 11070/DOC 11070 - AAMI Safe Currents Test Procedure and Data Sheet.
3.3 ITP 35001.PM – Preventative Maintenance Procedure for Model 8000 IV Pump.
3.4 DOC 11089 – Software Version / Case Labeling Matrix.

4.0 PROCEDURE

4.1 Fill in the Facility Name, Pump Serial Number, and Software Version to be installed:

Facility: _____ Pump Serial Number: _____

Upgrade to Software Version: _____

		PASS	**FAIL**
4.2	Update: Check each step, Pass or Fail, to the right as it is completed.		
4.2.1	Verify any hospital specific BioMed Option setting requirements before beginning.	_____	_____
4.2.2	Replace software with latest version. Reference SOP 11088.	_____	_____
4.2.3	Press "ON". Record the software version (Either during PROM update or via BMO 200) Ver. _____		
4.2.4	Check pump serial number. BIO OPT 201. Verify with Serial Number above.	_____	_____
4.3	Functional Checks:		
4.3.1	Plug unit into an AC outlet; verify the AC indicator is illuminated.	_____	_____
4.3.2	Perform "Additional Required Checks for this Facility Upgrade" Section 4.4.	_____	_____
4.3.3	Perform ITP 35001.PM – Preventative Maintenance Procedure.	_____	_____

(Note sections 6.3, 6.7, 6.8, and 6.11 of ITP 35001.PM may be omitted and section 6.6 may be abbreviated to just confirm the occurrence of the alarm rather than measure the alarm threshold if a full P.M. is not desired.)

4.3.4	Select OPTION 99 and ENTER. Verify the display indicates ALL CLR.	_____	_____
4.3.5	Reset all required hospital specific BioMed settings using the respective options.	_____	_____
4.3.6	Upon the completion and passing of all the above steps complete forms and return a copy of each to SIGMA International. Mail or Fax to : SIGMA International ATTN: Device Tracking Coordinator P.O. Box 0756 Medina, NY 14103 Fax: (585) 798-3909		

4.4 Additional Required Checks for Facility Upgrade: Approvals: (Eng) _____ (QA) _____

	Fill in any additional checks required for this upgrade ("N/A" if none Required)	**PASS**	**FAIL**
4.4.1	Replace case labels, as required, with the latest revision of respective labels. Label 40005: Rev. ____ Label 40006: Rev. ____ Label 40007: Rev. ____ Label 40011-1: Rev. ___	_____	_____
4.4.2	_____	_____	_____
4.4.3	_____	_____	_____

*Mark here if continued on back of Sheet ( )

NOTE: If the unit does not pass all the steps, contact the SIGMA Service Department for repair instructions.

Signature: _____ Date: _____

SERVICE MANUAL
SIGMA INTERNATIONAL
MODEL 8000 & 8000 *Plus*
INFUSION PUMPS
SECTION 2

SECTION 2 TECHNICAL DRAWINGS

2.0 External Features, Case

2.1 Functional Blocks - Block Diagram

2.2 Cables and Wiring

2.3 AC Line Circuit

2.4 Regulator PCB

2.5 Display PCB

2.6 Processor/Sensor PCB

2.7 Motor Assembly

2.8 Shaft Sensor

2.9 Pole Clamp

2.10 Pump Mechanism

2.11 Rear Case Assembly

2.12 Front Case Assembly

2.13 Final Assembly/Labels

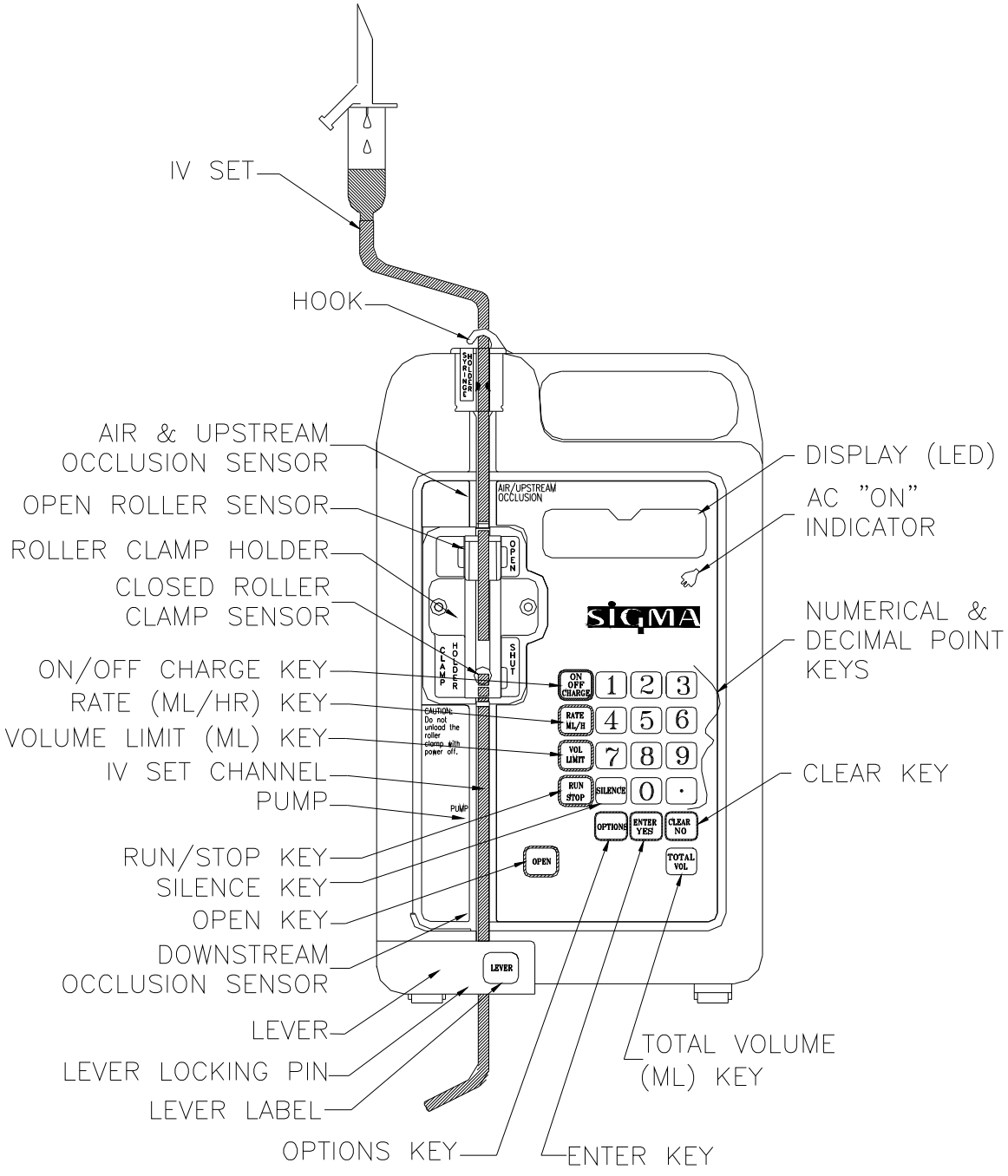
2.14 Keyboard

2.15 Pump/Motor Assembly

2.16 Roller Clamp Schematic

2.17 Upstream Occlusion Sensor Schematic

FRONT VIEW


IV SET
HOOK
AIR & UPSTREAM OCCLUSION SENSOR
OPEN ROLLER SENSOR
ROLLER CLAMP HOLDER
CLOSED ROLLER CLAMP SENSOR
ON/OFF CHARGE KEY
RATE (ML/HR) KEY
VOLUME LIMIT (ML) KEY
IV SET CHANNEL
PUMP
RUN/STOP KEY
SILENCE KEY
OPEN KEY
DOWNSTREAM OCCLUSION SENSOR
LEVER
LEVER LOCKING PIN
LEVER LABEL
OPTIONS KEY
ENTER KEY
TOTAL VOLUME (ML) KEY
CLEAR KEY
NUMERICAL & DECIMAL POINT KEYS
AC "ON" INDICATOR
DISPLAY (LED)
AIR/UPSTREAM OCCLUSION
SIGMA
ON OFF CHARGE
RATE ML/H
VOL LIMIT
RUN STOP
SILENCE
OPTIONS
ENTER YES
CLEAR NO
TOTAL VOL
OPEN
LEVER
PUMP
CAUTION: Do not unload the roller clamp with power off.

REAR VIEW

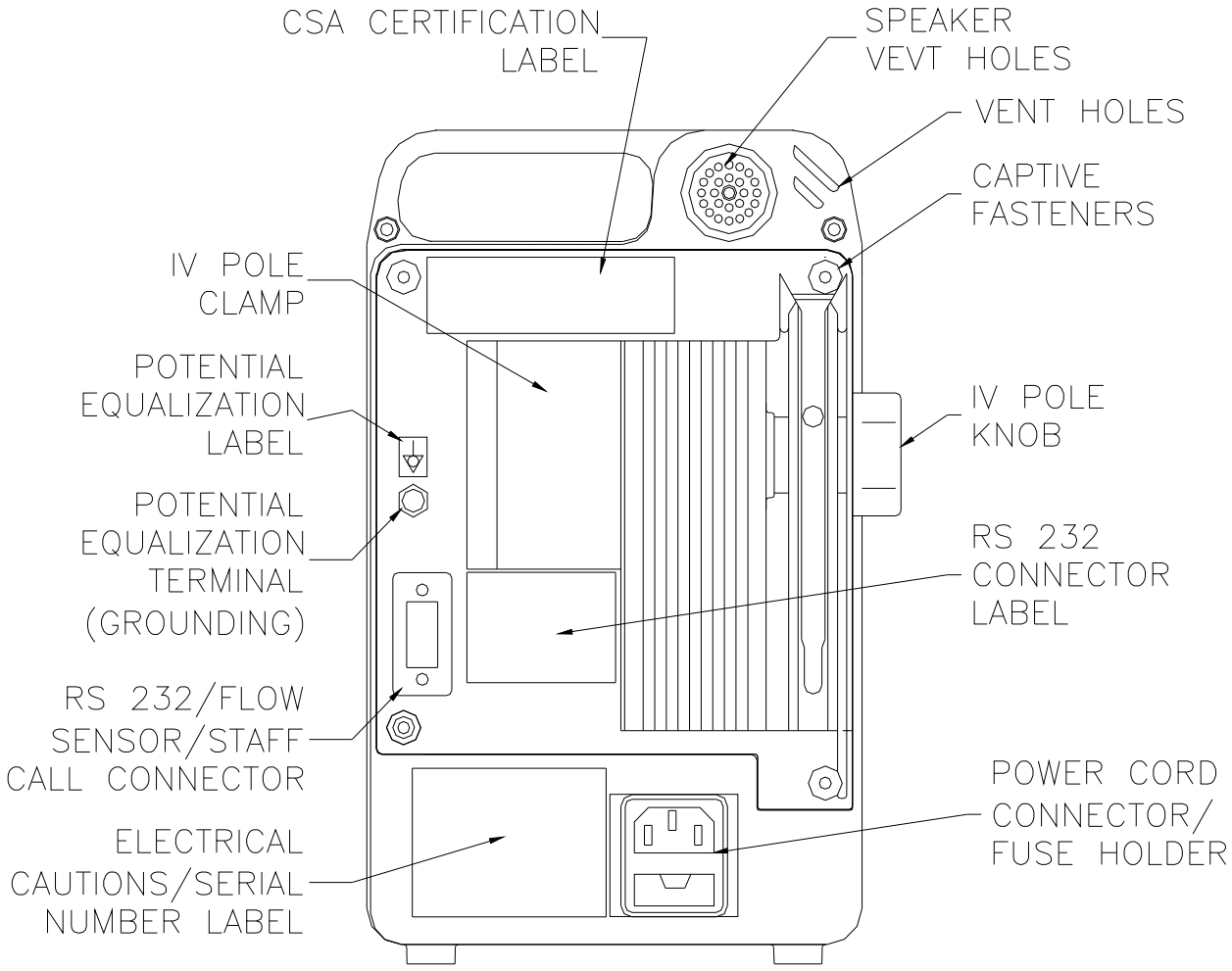

CSA CERTIFICATION LABEL
SPEAKER VEVT HOLES
VENT HOLES
CAPTIVE FASTENERS
IV POLE CLAMP
POTENTIAL EQUALIZATION LABEL
POTENTIAL EQUALIZATION TERMINAL (GROUNDING)
RS 232/FLOW SENSOR/STAFF CALL CONNECTOR
ELECTRICAL CAUTIONS/SERIAL NUMBER LABEL
IV POLE KNOB
RS 232 CONNECTOR LABEL
POWER CORD CONNECTOR/ FUSE HOLDER

FIGURE 2.1.0 BLOCK DIAGRAM

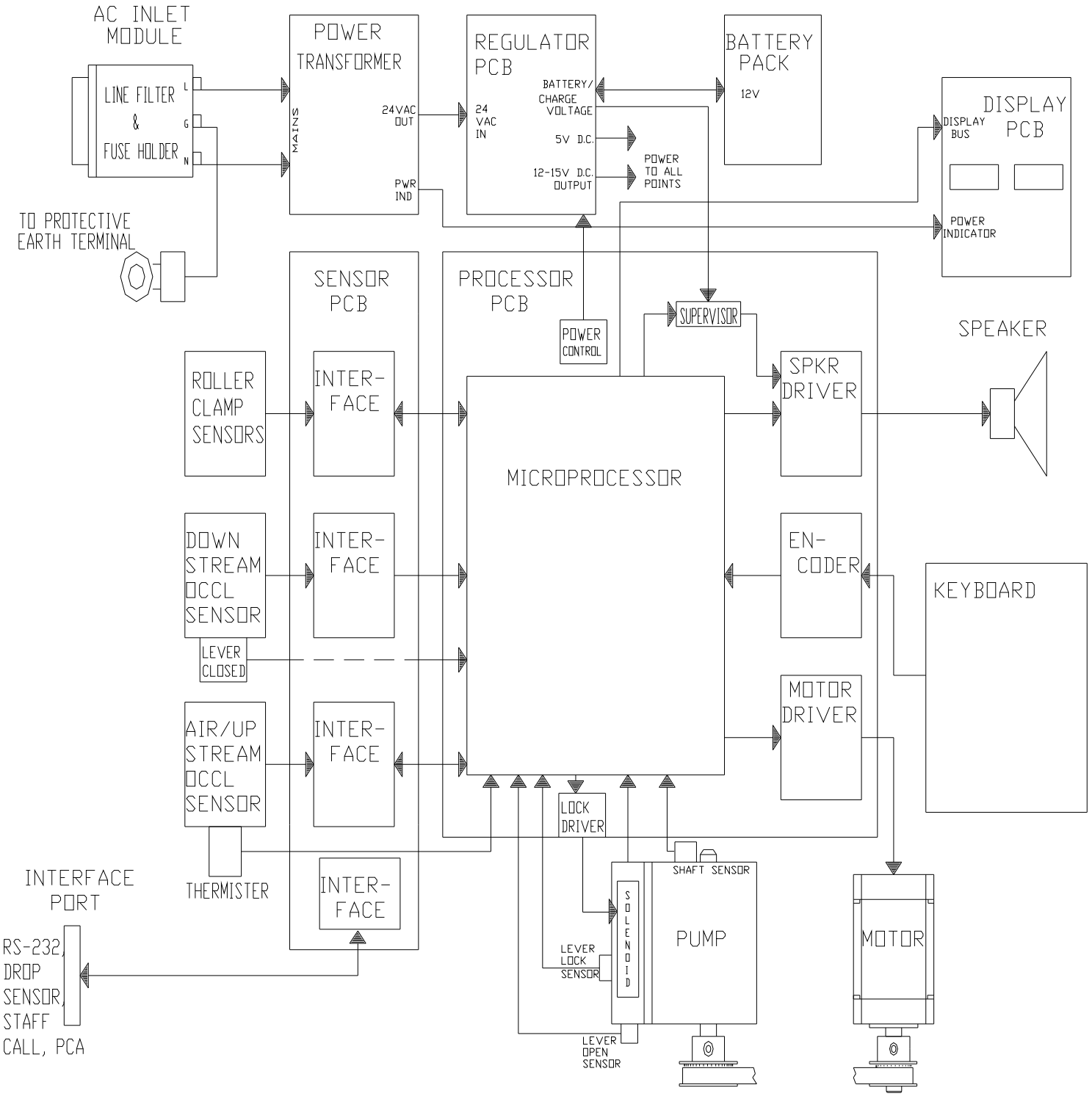


FIGURE 2.2.1 CABLE DIAGRAM

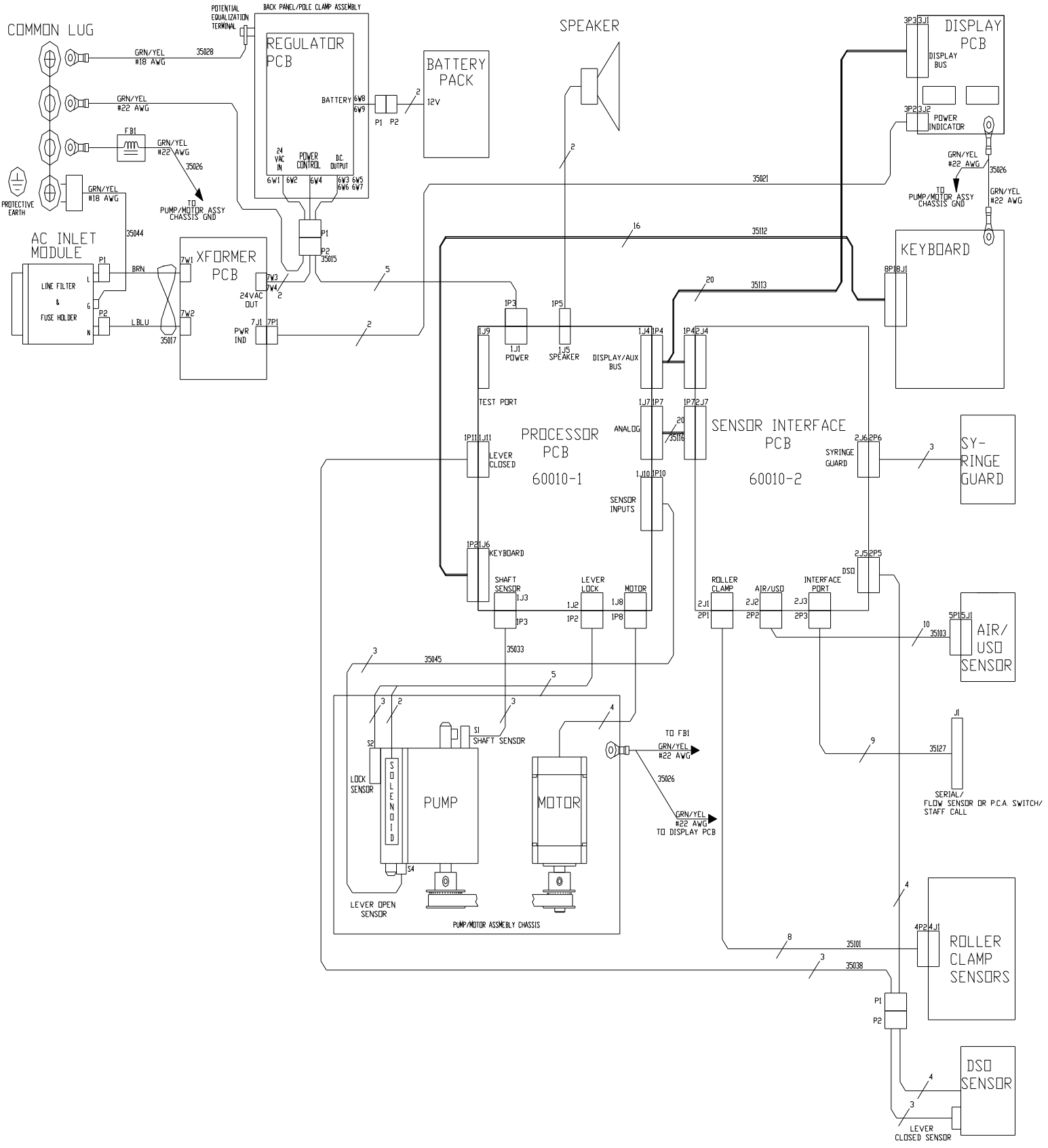


FIGURE 2.3.0 TRANSFORMER PCB SCHEMATIC (DWG 60009s1 Rev. F)

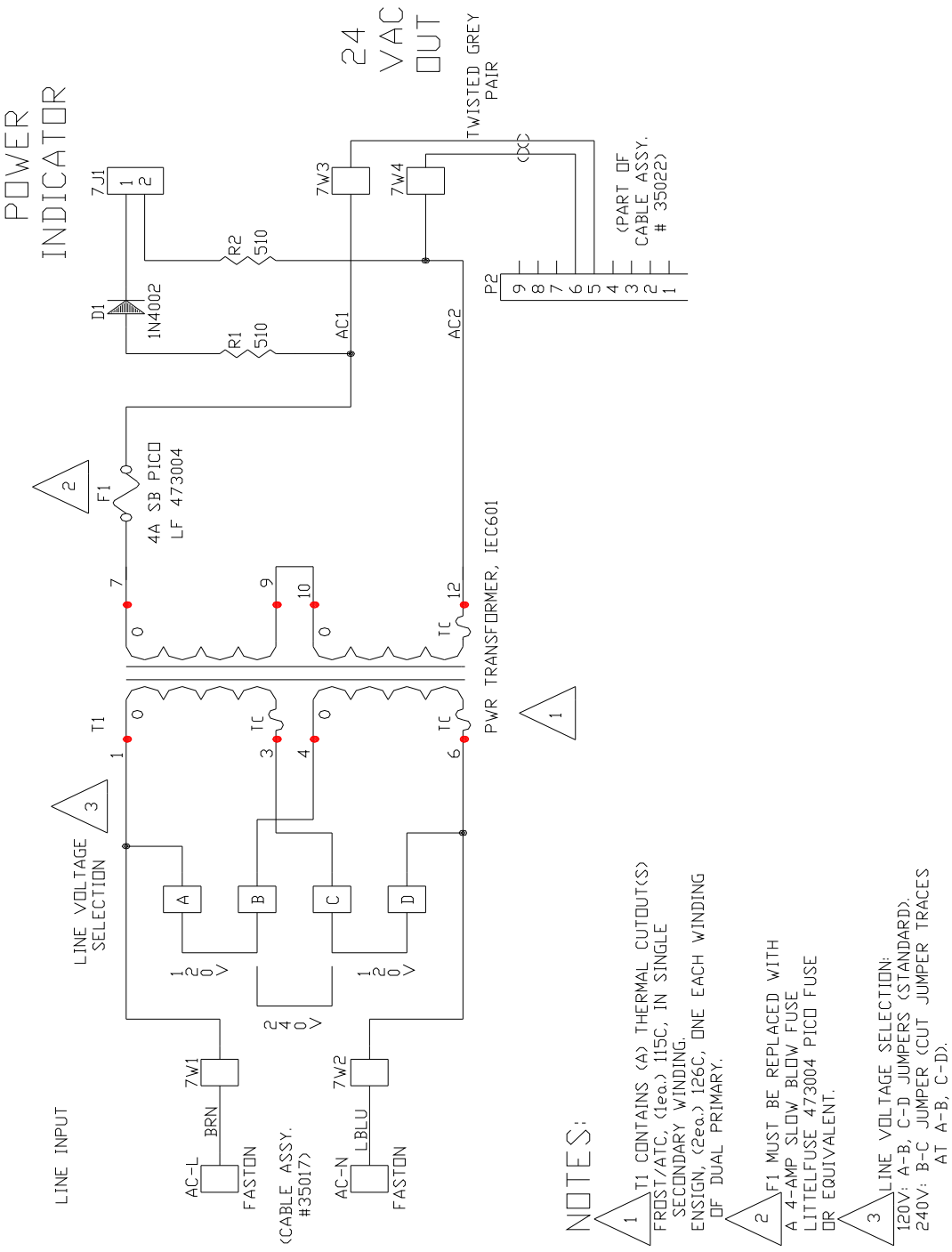
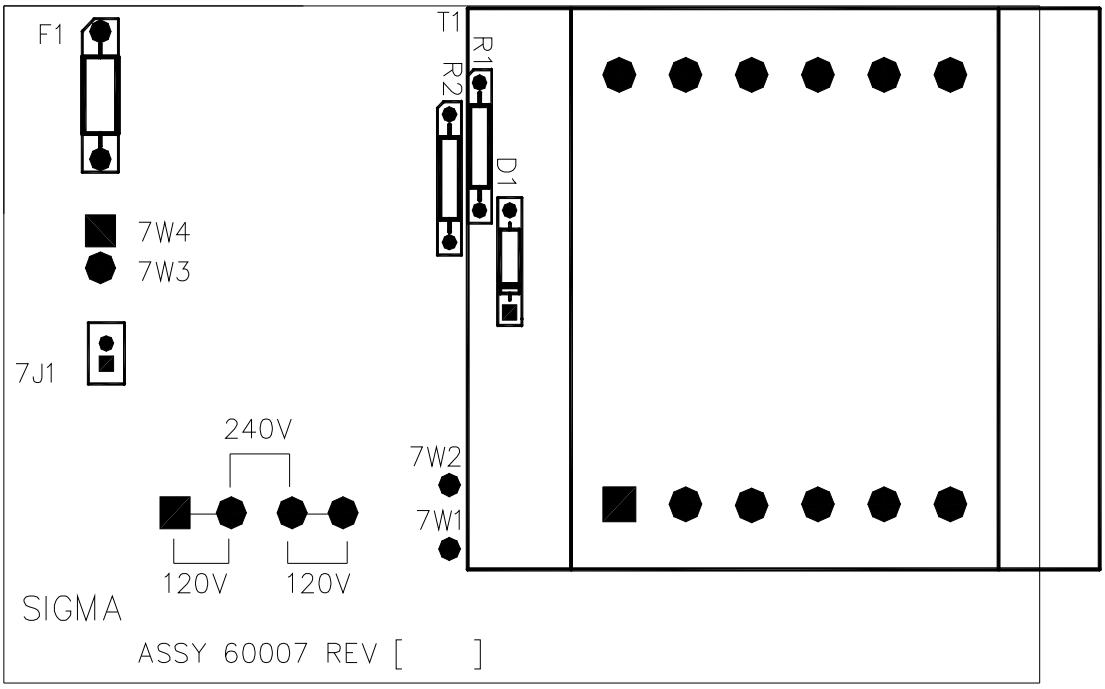


FIGURE 2.3.1 TRANSFORMER PCB LAYOUT (DWG 60007 Rev. G)



	AR	85089	HUMISEAL TYPE 1BB
CBL3	REF	35017	WIRE HARNESS
CBL2	REF	35022	POWER SUPPLY CABLE
CBL1	REF	35021	LED INDICATOR CABLE
ALL CABLE & WIRE ASSEMBLIES TO BE INSTALLED AT SIGMA			
7J1	1	30002	HEADER 2 PIN
T1	1	55001	TRANSFORMER
F1	1	25302	FUSE 4A SB PICO
D1	1	70161	DIODE 1N4002
R2	1	16024	RES 510 OHM 1/4W 5%
R1	1	16024	RES 510 OHM 1/4W 5%
PCB	1	60008	TRANSFORMER PCB BLANK
ITEM	QTY	P/N	DESCRIPTION

BILL OF MATERIALS

Replace T1 only with the transformer above. Substitution violates the Certification of this product and may compromise product safety.

FIGURE 2.4.0 REGULATOR PCB SCHEMATIC (DWG 60003 Rev I)

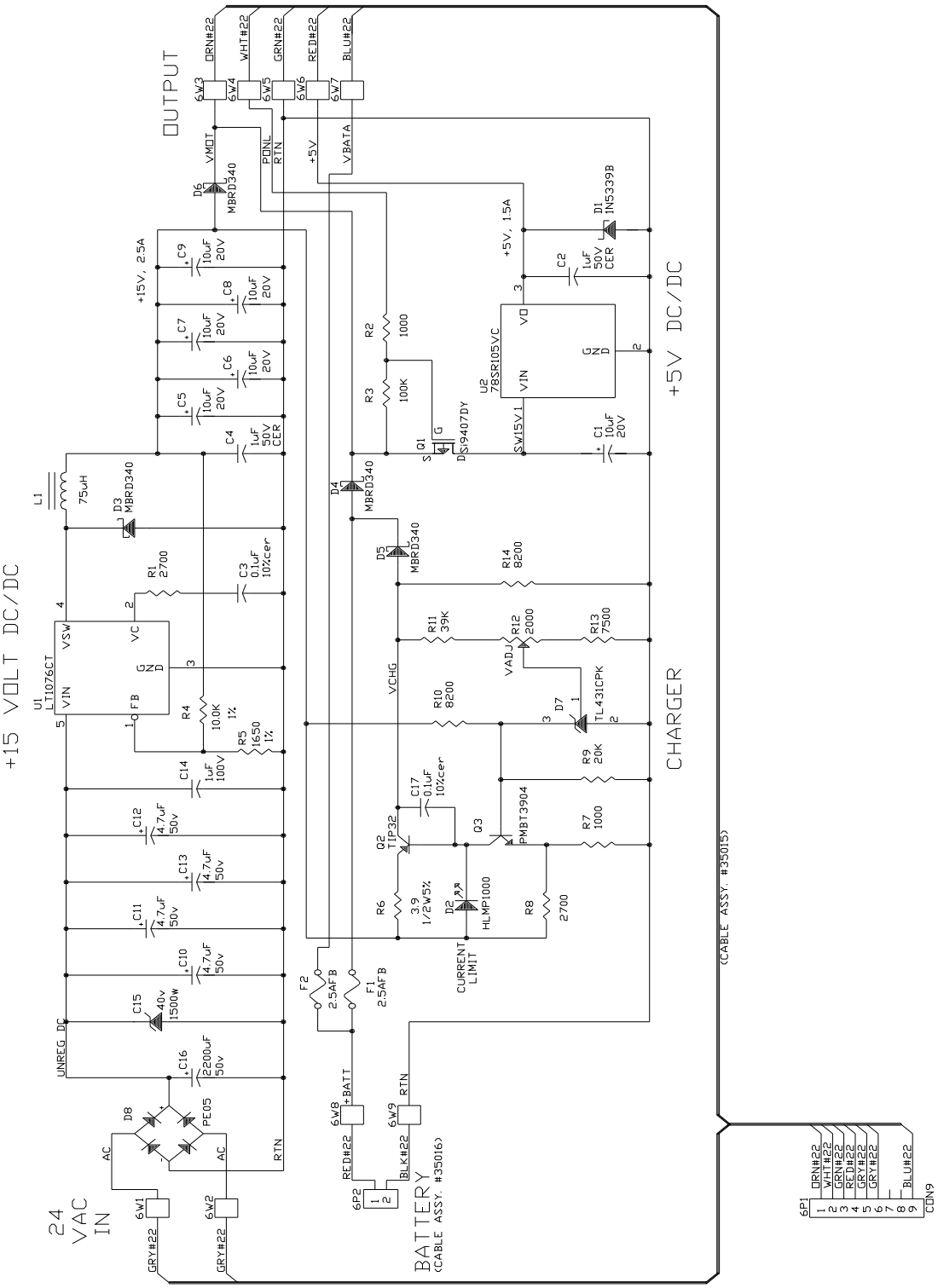
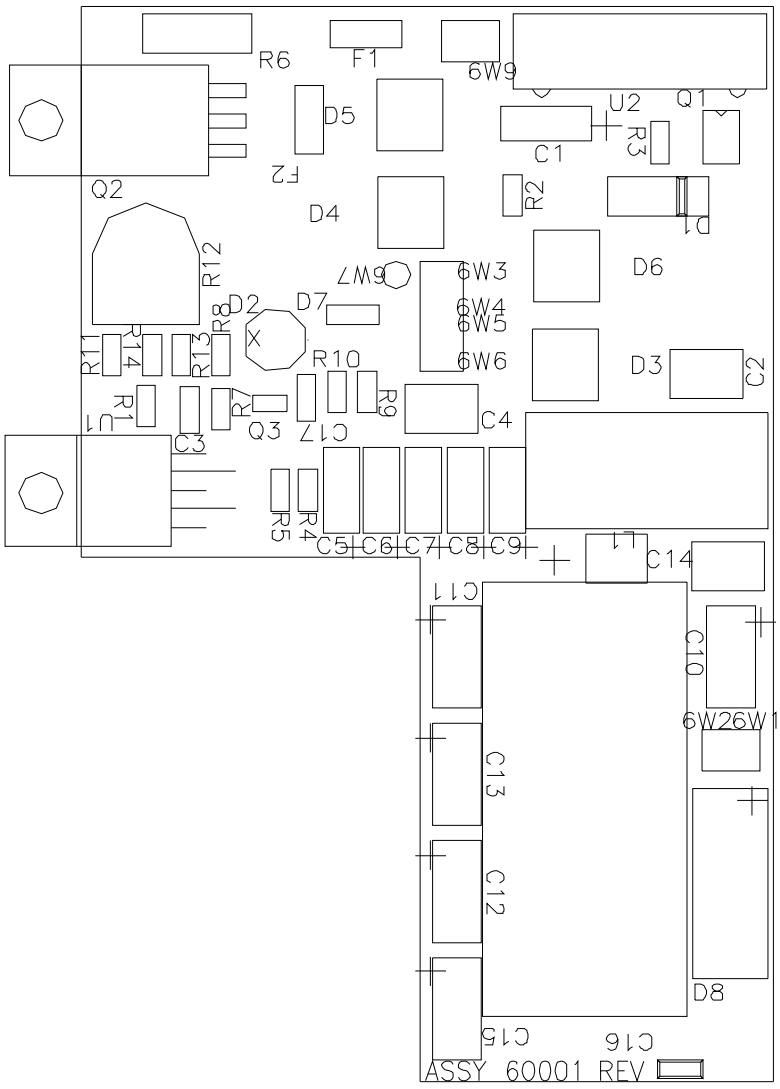


FIGURE 2.4.1 REGULATOR PCB LAYOUT (DWG 60001 Rev. E)



CBL2	--	1	--	35141-1	BATTERY HARNESS (8) (10)
CBL2	1	--	--	35141	BATTERY HARNESS (8) (10)
CBL2	--	--	1	35016	BATTERY HARNESS (8)
CBL1	--	1	--	35140-1	REGULATOR HARNESS (8)
CBL1	1	--	--	35140	REGULATOR HARNESS (8)
CBL1	--	--	1	35015	REGULATOR HARNESS (8)
L1	1	1	1	25304	CHOKE 75 uh 2A TOROID
F2	1	1	1	25303	FUSE 2.5A FAST BLOW
F1	1	1	1	25303	FUSE 2.5A FAST BLOW
U2	1	1	1	25309	IC 3 LEAD REGULATOR
U1	1	1	1	25308	IC REGULATOR T220
Q3	1	1	1	25202	TRANS SOT23 NPN
Q2	1	1	1	25201	TRANS TO220 5A 60V PNP
Q1	1	1	1	25204	TRANS MOSFET 60V .18A
D8	1	1	1	87245	BRIDGE RECT 5A 50V
D7	1	1	1	25101	DIODE REF ADJ TL431
D6	1	1	1	25103	DIODE 3A 40V SCHOTTKY
D5	1	1	1	25103	DIODE 3A 40V SCHOTTKY
D4	1	1	1	25103	DIODE 3A 40V SCHOTTKY
D3	1	1	1	25103	DIODE 3A 40V SCHOTTKY
D2	1	1	--	25113	DIODE 1.2 V REFERENCE
D2	--	--	1	25005	DIODE T1 RED LED
D1	1	1	1	25107	DIODE 5.6V 5W ZENER
C18	1	1	--	11017	CAP 0.1 uf 50V CER 0805 PKG
C17	1	1	1	11001	CAP 0.1 uf 50V CER.
C16	1	1	1	12001	CAP 2200 uf 50V ALUM. AXIAL
C15	1	1	1	25116	DIODE 40v 1500w UNI. TRANS. VOLT SUPP
C14	1	1	1	11040	CAP 1 uf 10vdc CER.
C13	1	1	1	10002	CAP 4.7 uf 50V TANT
C12	1	1	1	10002	CAP 4.7 uf 50V TANT
C11	1	1	1	10002	CAP 4.7 uf 50V TANT
C10	1	1	1	10002	CAP 4.7 uf 50V TANT
C9	1	1	1	10001	CAP 10uf 20V TANT
C8	1	1	1	10001	CAP 10uf 20V TANT
C7	1	1	1	10001	CAP 10uf 20V TANT
C6	1	1	1	10001	CAP 10uf 20V TANT
C5	1	1	1	10001	CAP 10uf 20V TANT
C4	1	1	1	11009	CAP 1 uf 50V CER.
C3	1	1	1	11001	CAP 0.1 uf 50V CER.
C2	1	1	1	11009	CAP 1 uf 50V CER.
C1	1	1	1	10001	CAP 10uf 20V TANT
R14	1	1	1	15018	RES 8.25 K 1/4 W 1%
R13	1	1	1	15017	RES 7.5 K 1/4 W 1%
R12	1	1	1	17001	POTENTIOMETER 2 K 1 TURN
R11	1	1	1	15016	RES 39.2 K 1/4 W 1%
R10	1	1	1	15018	RES 8.25 K 1/4 W 1%
R9	1	1	1	15014	RES 20 K 1/4 W 1%
R8	1	1	1	15015	RES 2.74 K 1/4 W 1%
R7	1	1	1	15013	RES 1 K 1/4 W 1%
R6	1	1	--	17007	RES 2.0 OHM 1/2 W 5%
R6	--	--	1	16001	RES 3.9 OHM 1/2 W 2%
R5	1	1	1	15020	RES 1.65 K 1/4 W 1%
R4	1	1	1	15001	RES 10 K 1/4 W 1%
R3	1	1	1	15019	RES 100 K 1/4 W 1%
R2	1	1	1	15013	RES 1 K 1/4 W 1%
R1	1	1	1	15015	RES 2.74 K 1/4 W 1%
PCB	1	1	1	60002	REGULATOR PCB BLANK
ITEM	QTY	QTY	QTY	P/N	DESCRIPTION
	60001-2	60001-1	60001		

BILL OF MATERIALS

FIGURE 2.5.0 DISPLAY PCB SCHEMATIC (DWG 60006s1 Rev. C)

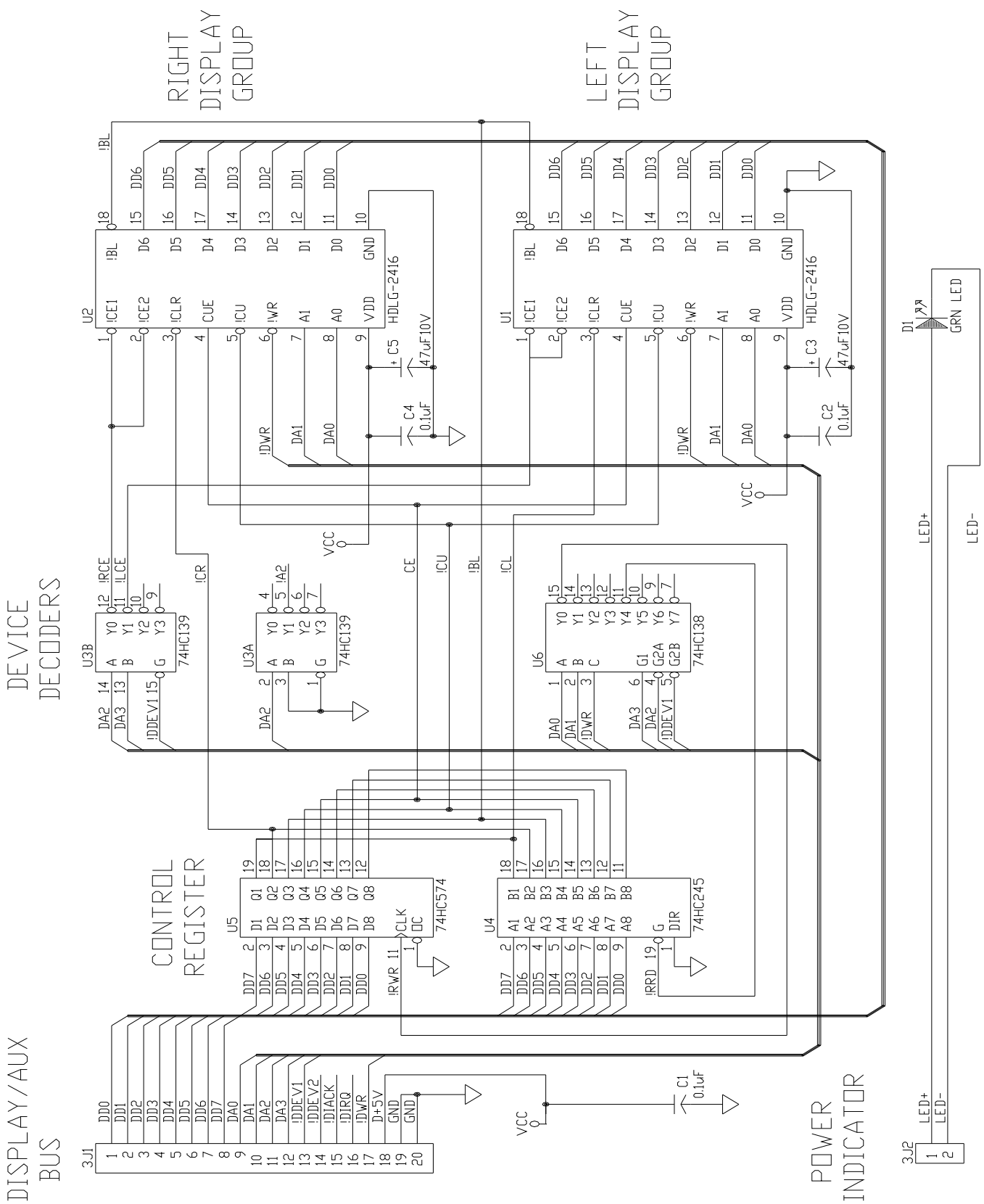
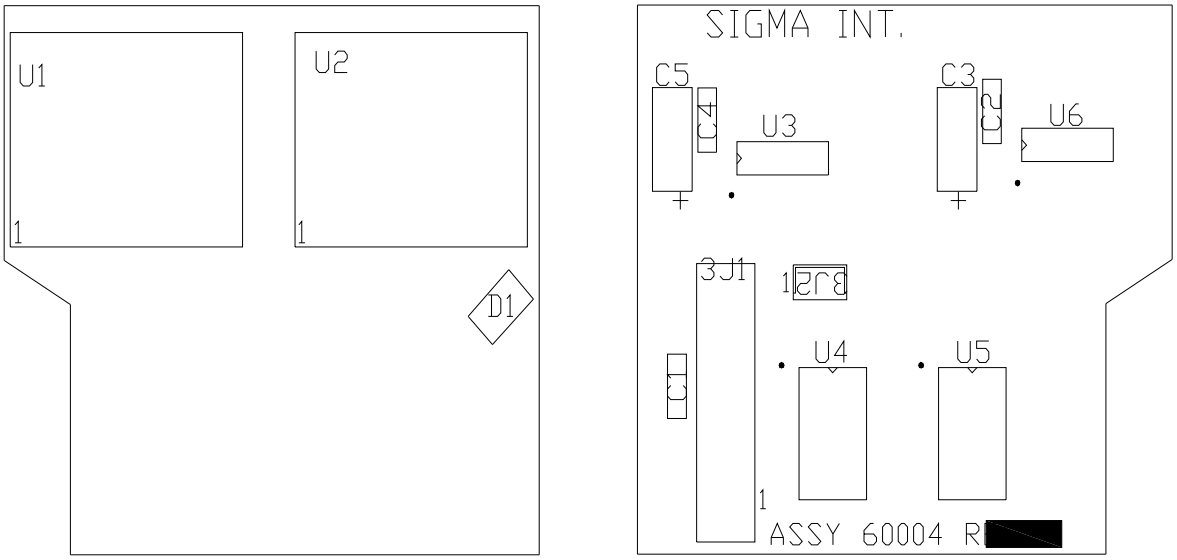


FIGURE 2.5.1 DISPLAY PCB LAYOUT (DWG 60004 Rev. D)



FRONT VIEW BACK VIEW

FIGURE 2.5.2 DISPLAY PCB ASM, BOM

REF	QTY	P/N	DESCRIPTION
CBL2	REF	35113	DISPLAY PCB W/EXT (8)
CBL1	REF	35021	LED INDICATOR CABLE (8)
3J2	1	30002	HEADER 2 PIN
3J1	1	30007	HEADER 20 PIN
U6	1	20005	IC 74HC138
U5	1	20004	IC 74HC574
U4	1	20003	IC 74HC245
U3	1	20002	IC 74HC139
U2	1	25002	DISPLAY – GREEN
U1	1	25002	DISPLAY – GREEN
D1	1	25001	LED GREEEN RECT
C5	1	10005	CAP 47uf 10V 20% TANT
C4	1	11001	CAP .1uf 50V 20% CER
C3	1	10005	CAP 47 uf 10V 20% TANT
C2	1	11001	CAP .1uf 50V 20% CER
C1	1	11001	CAP .1uf 50V 20% CER
PCB	1	60005	PCB BLANK

BILL OF MATERIALS

FIGURE 2.6.0 PROCESSOR PCB SCHEMATIC (DWG 60012s1 Rev R) (CONTACT SIGMA FOR FULL SCALE SCHEMATIC)

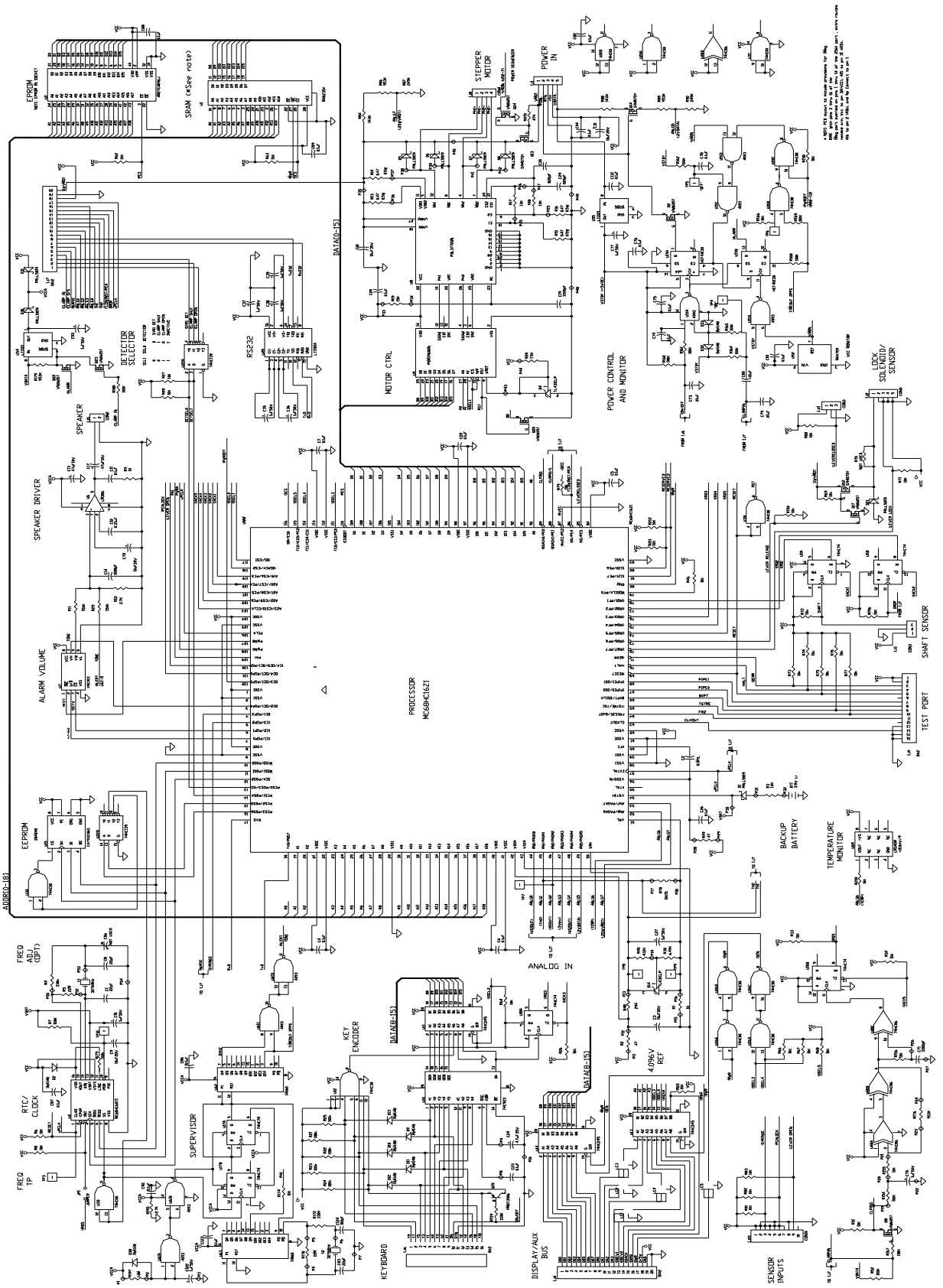


FIGURE 2.6.0 SENSOR PCB SCHEMATIC (DWG 60012s2 Rev R) (CONTACT SIGMA FOR FULL SCALE SCHEMATIC)

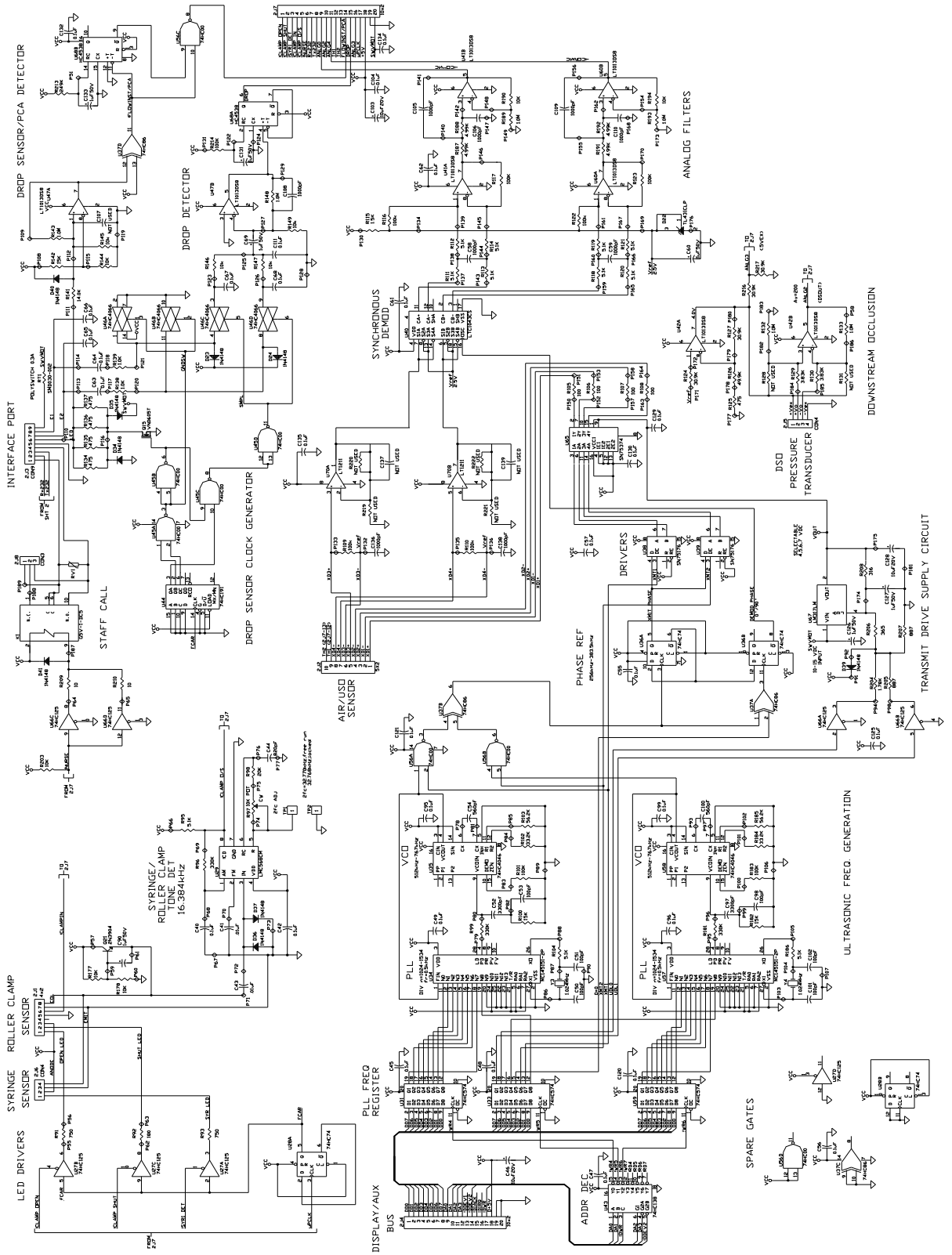


FIGURE 2.6.1 PROCESSOR/SENSOR PCB LAYOUT (DWG 60010 Rev. P)

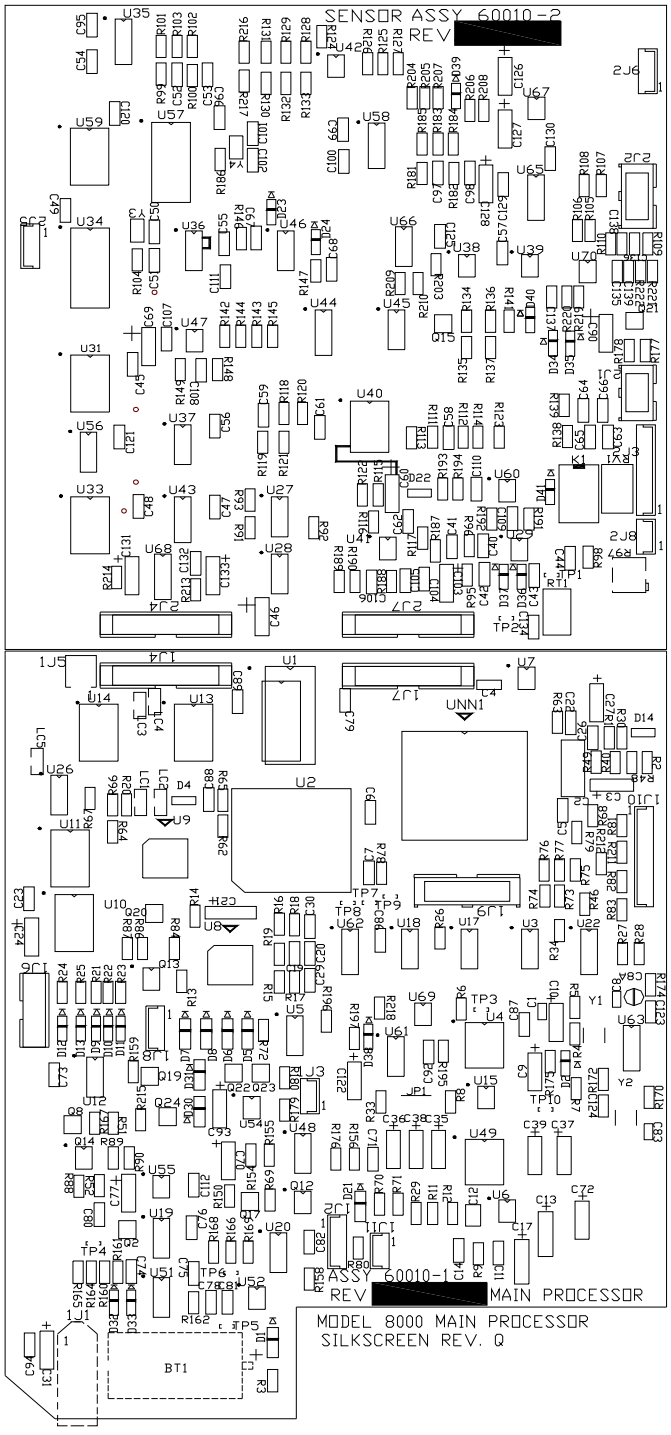


FIGURE 2.6.2 PROCESSOR/SENSOR PCB ASM, BOM

Item	Quant.	P/N	Ref.	Description/Manufacturer
1.	1	55003	BT1	BATTERY,3.6V,0.75Ah,1/2AA,Li/TCl
2.	3	11002	C1,C8,C83	CAP,cer,22pf,100V,C0G,5% SM
3.	18	10003	C10,C27,C35,C36, C37,C38,C39,C60,C6 9,C70,C77,C90,C93, C122,C126, C127,C131,C133	CAP, tant, 1uf, 50V, 20% SM
4.	1	11010	C12	CAP,cer,.33uf,50V,20%,X7R/Z5U SM
5.	2	10005	C13, C17	CAP,tant,47uf,10V,20% SM
6.	10	11007	C14,C58,C59,C105,C 106,C108,C109,C110 ,C136,C138	CAP,cer,1000pf,50V,10%,C0G SM
7.	4	11008	C19,C52,C71,C97	CAP,cer,3300pf,50V,10%,C0G SM
8.	1	12002	C2	CAP,myl,0.1uf,100V,10% TH
9.	1	10004	C21	CAP,tant,10uf,35V,20% SM
10.	1	10006	C24	CAP,tant,4.7uf,35v,10% TH
11.	3	11006	C29,C30,C44	CAP,cer,820pf,100v,10%,C0G SM
12.	7	10001	C3,C9,C31,C46, C72,C103, C128	CAP,tant,10uf,20V,20% SM
13.	53	11001	C4,C5,C6,C7,C11,C2 0,C22,C23,C26,C40, C42,C45,C47,C48,C4 9,C55,C56,C57,C61, C62,C63,C64,C65,C6 6,C67,C68,C74,C75, C76,C78,C81,C82,C8 6,C87,C88,C89,C92, C94,C95,C96,C99,C1 04,C111,C112, C120,C123,C129, C130,C132,C134, C135,C121,	CAP,cer,0.1uf,50V,20%,X7R/Z5U SM
14.	5	11005	C41,C43,C73,C79,C8 0	CAP,cer,.01uf,100v,10%,X7R TH
15.	7	11003	C50,C51,C53,C98,C1 01,C102,C124	CAP,cer,100pf,100V,5%,C0G SM
16.	2	11004	C54,C100	CAP,cer,560pf,100V,5%,C0G SM
17.	8	25104	D1,D5,D6,D7,D8, D21,D30,D31	DIODE,ref schtky 1A,40V SM
18.	18	25102	D2,D9,D10,D11, D12,D13,D23,D24,D3 2,D33,D34,D35,D36, D37,D38,D39,D40,D4 1	DIODE,sig 1N4148,SOD80-C SM
19.	3	25101	D4,D14,D22	DIODE,ref,adj,TL431 SM
20.	1	25319	K1	RELAY SM
21.	5	25317	LC1,LC2,LC3, LC4,LC5	EMI FILTER CHIP SM
22.	1	60011	PCB	PCB BLANK
23.	3	25204	Q12,Q13,Q14	TRANS,MOSfet,p-ch,enh,60V,2.4A SM
24.	1	25207	Q19	TRANSISTOR SM
25.	8	25203	Q2,Q8,Q15,Q17, Q20,Q22,Q23,Q24	TRANS,MOSfet,n-ch,enh,60V,.18A SM
26.	1	25202	Q21	SM TRANS,2N3904

FIGURE 2.6.2 PROCESSOR/SENSOR PCB ASM, BOM

Item	Quant.	P/N	Ref.	Description/Manufacturer
27.	4	16003	R1,R9,R209,R210	RESISTOR, 10Ω, 1/4W, 5%, CF SM
28.	2	15028	R102,R184	RESISTOR, 33.2Ω, 1/4W, 1% MF SM
29.	2	15029	R103,R185	RESISTOR, 56.2KΩ, 1/4W, 1% MF SM
30.	4	16019	R105,R106,R107, R108	RESISTOR, 100Ω, 1/4W, 5% CF SM
31.	2	16007	R11,R29	RESISTOR, 150KΩ, 1/4W, 5%, CF SM
32.	2	16010	R12,R195	RESISTOR, 2.7KΩ, 1/4W, 5%, CF SM
33.	4	15005	R124,R127,R216, R217	RESISTOR, 30.9KΩ, 1/4W, 1%, MF SM
34.	5	15006	R125,R134,R135, R136,R137	RESISTOR, 475Ω , 1/4W, 1%, MF SM
35.	1	15009	R126	RESISTOR, 49.9KΩ, 1/4W, 1%, MF SM
36.	2	15032	R129,R130	RESISTOR, 3.83KΩ, 1/4W,1%, MF SM
37.	4	16014	R13,R14,R15,R16	RESISTOR, 0.47Ω, 1/4W, 5%, CF SM
38.	7	15012	R132,R133,R143, R148,R189,R193, R197	RESISTOR, 1.0MΩ, 1/4W,1%,MF SM
39.	4	15008	R187,R188,R191, R192	RESISTOR, 4.99KΩ, 1/4W, 1%, MF SM
40.	4	16006	R19,R100,R142, R182	RESISTOR, 15KΩ, 1/4W, 5%, CF SM
41.	2	16013	R2,R49	RESISTOR, 47Ω, 1/4W, 5%, CF SM
42.	2	16025	R20,R115	RESISTOR, 1.5KΩ, 1/4W, 5% CF SM
43.	1	15024	R204	RESISTOR, 1.78KΩ, 1/4W, 1% MF SM
44.	2	15025	R205,R207	RESISTOR, 887Ω, 1/4W, 1% MF SM
45.	1	15026	R206	RESISTOR, 365Ω, 1/4W, 1% MF SM
46.	1	15033	R208	RESISTOR, 316Ω, 1/4W, 1%, MF SM
47.	1	16016	R215	RESISTOR, 47KΩ, 1/4W, 5%, CF SM
48.	5	16017	R3,R17,R18, R138,R139	RESISTOR, 1KΩ, 1/4W, 5%, CF SM
49.	1	15021	R30	RESISTOR, 6.49KΩ, 1/4W, 1% MF SM
50.	6	16011	R4,R96,R99, R159,R172,R181	RESISTOR, 330KΩ, 1/4W, 5%, CF SM
51.	1	15022	R40	RESISTOR, 4.12KΩ, 1/4W, 1% MF SM
52.	1	15023	R48	RESISTOR, 294Ω, 1/4W, 1% MF SM
53.	2	16009	R5,R170	RESISTOR, 22MΩ, 1/4W, 5%, CF SM
54.	50	16004	R6,R8,R26,R27, R28,R33,R34,R46,R51,R62,R63,R64,R65, R66,R67,R68,R69,R71,R72,R73,R74,R75, R76,R77, R79,R80,R81,R82,R83,R144,R145, R146,R147, R149,R150,R155, R156, R158,R166, R174,R177,R178, R190,R194,R196, R203,R211,R212, R218	RESISTOR, 10KΩ, 1/4W, 5%, CF SM
55.	27	16005	R7,R21,R22,R23, R24,R25,R52,	RESISTOR, 100KΩ, 1/4W, 5%, CF SM

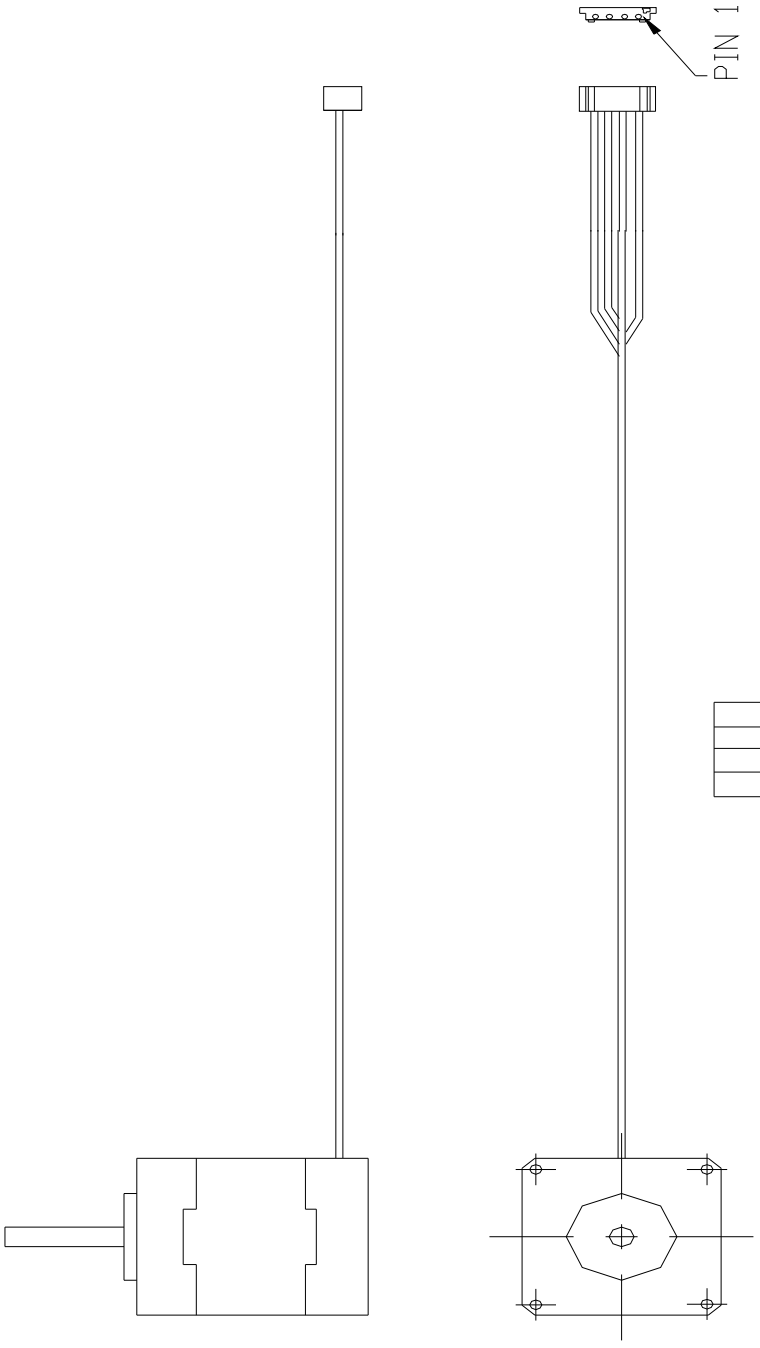
FIGURE 2.6.2 PROCESSOR/SENSOR PCB ASM, BOM

Item	Quant.	P/N	Ref.	Description/Manufacturer
			R101,R109,R110, R116,R117,R122, R123,R154,R160, R161,R162,R164, R165,R167,R168, R169,R175,R180, R183,R214	
56.	1	15001	R78	RESISTOR, 10KΩ, 1/4W, 1%
57.	4	15011	R86,R89,R176, R179	RESISTOR, 953KΩ, 1/4W, 1%, MF SM
58.	3	15004	R87,R90,R213	RESISTOR, 249KΩ, 1/4W, 1%, MF SM
59.	1	15031	R84, R88, R141	RESISTOR, 14K, 1/4W, 1% SM
60.	2	16020	R91,R93	RESISTOR, 750Ω, 1/4W, 5%, CF SM
61.	1	16022	R92	RESISTOR, 180Ω, 1/4W, 5% CF SM
62.	11	16018	R95,R104,R111, R112,R113,R114, R118,R119,R120, R121,R186	RESISTOR, 5.1KΩ, 1/4W, 5%, CF SM
63.	1	17002	R97	POTENTIOMETER, 10KΩ SM
64.	1	16008	R98	RESISTOR, 20KΩ, 1/4W, 5%, CF SM
65.	1	25310	RT1	POLYSWITCH, .03 A TH
66.	1	25357	R70	FUSE 1.5 AMP 1206 pkg
67.	1	25316	RU1	VARISTOR, V360CH8
68.	1	20012	U10	IC, KYBDCTRL, 74C923 SM
69.	3	20003	U11,U13,U14	IC, OCTBUF, 74HC245 SM
70.	1	20013	U12	IC, 8INNAND, 74HC30 SM
71.	1	20014	U15	IC, SER EEPROM, 2Kx8 SM
72.	1	20016	U19	IC, DDFF, CD4013B SM
73.	1	20002	U22	IC, D2TO8ENC. 74C139 SM
74.	2	20019	U27,U66	IC, QTRISTATE, 74HC125 SM
75.	1	20023	U29	IC, TONEDETECT, LMC568 SM
76.	5	20032	U3,U20,U26,U45, U56	IC, QNAND, 74HC00 SM
77.	3	20004	U31,U33,U59	IC, 8BLATCH, 74HC574 SM
78.	2	20024	U34,U57	IC, PLL MC145151 SM
79.	1	20021	U35,U58	IC, VCO/PLL, 74HC4046 SM
80.	2	20017	U37,U48	IC, QXOR, 74HC86 SM
81.	2	20028	U38,U39	IC, DIFFBUS SN75176 SM
82.	1	20006	U4	IC, RTC, 68HC1621 SM
83.	1	20026	U40	IC, SWCAPAMP, LTC1043 SM
84.	4	20025	U41,U42,U47,U60,	IC, DOPAMP, LT1013 SM
85.	1	20005	U43	IC, 74HC138 SM
86.	1	20020	U44	IC, 4BITUPDN 74HC191 SM
87.	1	20022	U46	IC, QSWITCH, 74HC4066 SM
88.	1	20027	U49	IC, RS232INT, MAX232 SM
89.	5	20007	U5,U17,U18, U28,U36	IC, DDFF, 74HC74 SM
90.	1	20034	U51, U61	IC, MC14093 SM
91.	1	20035	U52	IC, MAX709 SM
92.	2	20033	U54,U55	IC, LT1121CS8-5 SM LINEAR TECH LT1121CS8-5
93.	1	20008	U6	IC, PWRAMP, LM386M-1 SM
94.	2	20036	U62,U63	IC 4060 SM

FIGURE 2.6.2 PROCESSOR/SENSOR PCB ASM, BOM

Item	Quant.	P/N	Ref.	Description/Manufacturer
95.	1	20038	U65	IC SN75374 SM
96.	1	20039	U67	IC LM317LM SM
97.	1	20040	U68	IC 74HC4538 SM
98.	1	20041	U69	IC LM34DM SM
99.	1	20042	U70	IC LT1211 SM
100.	1	20010	U8	IC, MOTDRV, PBL3772QN SM
101.	1	20009	U7	IC, EEPOT, 10K, X9C103 34SM
102.	1	20011	U9	IC, MOTCTRL, PBM3960QN SM
103.	1	30016	U2A	SOCKET, 44-PIN FOR U2
104.	1	55072		LITHUM BATTERY REFERENCE U1
105.	1	20029	U1	BATTERY BACKED RAM
106.	1	20043	U2	IC EPROM 256x16 4 MEG
107.	1	20029	UNN1	IC, uCONTR,16MHz,MC68HC16Z1 SM
108.	2	25312	Y1,Y2	XTAL, 32.768kHz SM
109.	2	25313	Y3,Y4	CERAMIC RESONATOR, 1.024MHz TH
110.	1	30013	1J1	PLUG, 5-PIN TH
111.	1	30003	1J10	HEADER, 10-P,2mm pc pin hdr TH
112.	5	30036	1J1P	PIN, PROCESS PCB TH
113.	1	30011	1J2	HEADER,5-P,V,2mm pc pin hdr TH
114.	1	30017	1J5	HEADER,2-P,V,2mm pc pin RT angle TH
115.	1	30008	1J6	HEADER,16-P,V,2mm pc pin hdr TH
116.	1	30010	2J1	HEADER,8-P,V,2mm pc pin hdr TH
117.	1	30009	2J2	HEADER,10-P,V,2mm pc pin hdr TH
118.	1	30012	2J3	HEADER,9-PIN, Fem, 2mm TH
119.	3	30020	1J3,1J11,2J8	HEADER,3-P TH
120.	3	30006	1J8,2J5,2J6	HEADER,4-P,V,2mm pc pin hdr TH
121.	4	30007	1J4,1J7,2J4,2J7	HEADER,20-P,RA,2mm pc pin hd TH

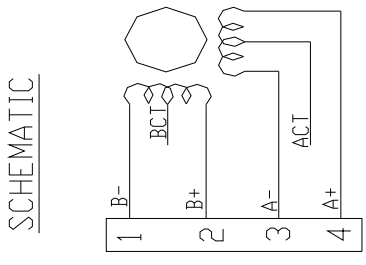
FIGURE 2.7.1 MOTOR ASSEMBLY CABLE (DWG 35032 Rev. D) AND
FIGURE 2.7.2 MOTOR ASSEMBLY BOM & WIRE COLORS FOR SCHEMATIC

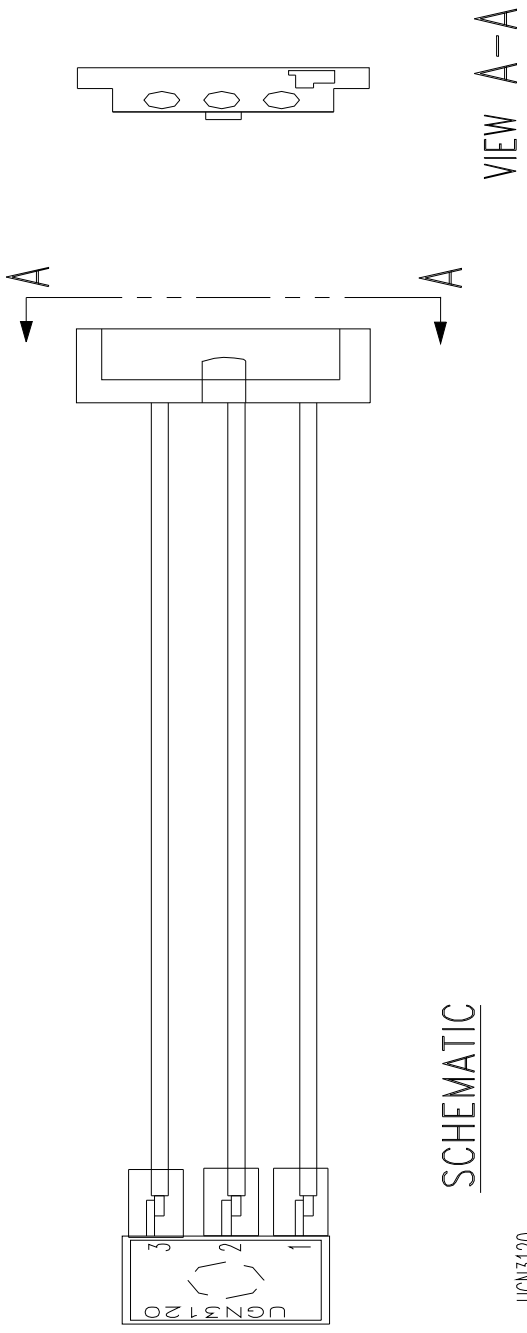


ITEM	P/N	QTY	DESCRIPTION
2	30022	1	Connector 4 PIN
1	55013	1	Stepper Motor

WIRE COLORS

MANUF	A+	ACT	A-	B+	BCT	B-
MYCOM	RED	BRN	WHT	YEL	BRN	BLU





ITEM	P/N	QTY	DESCRIPTION
7			
6	90007	AR	SOLDER
5			
4	35203	3	SHRINK-ø1/16 x 3/4"
3	35107	3	WIRE- 26 awg (wht)
2	30035	1	Conn. 3 PIN
1	70041	1	Sensor- Hall effect

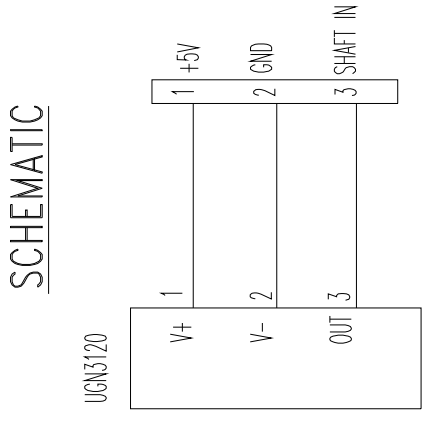
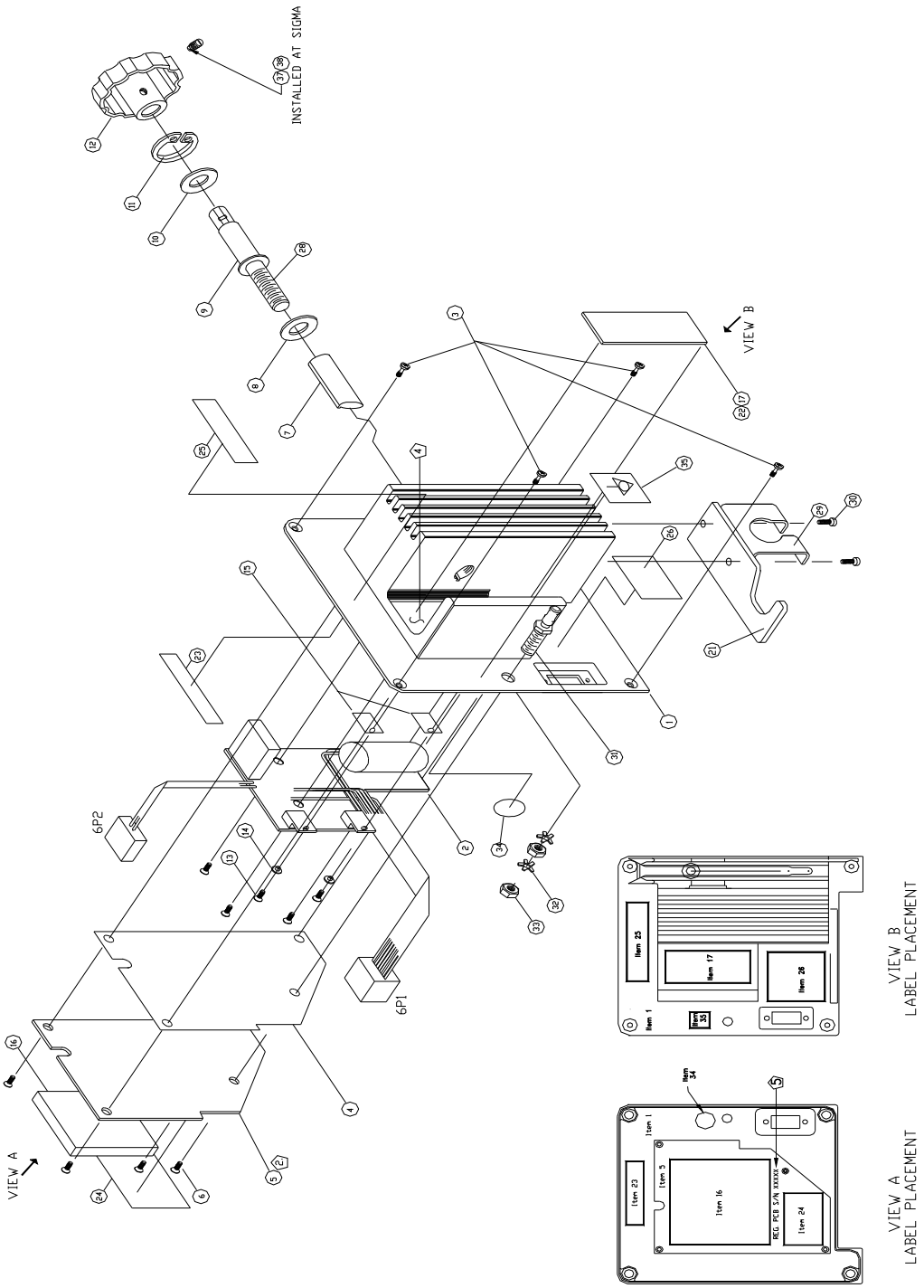


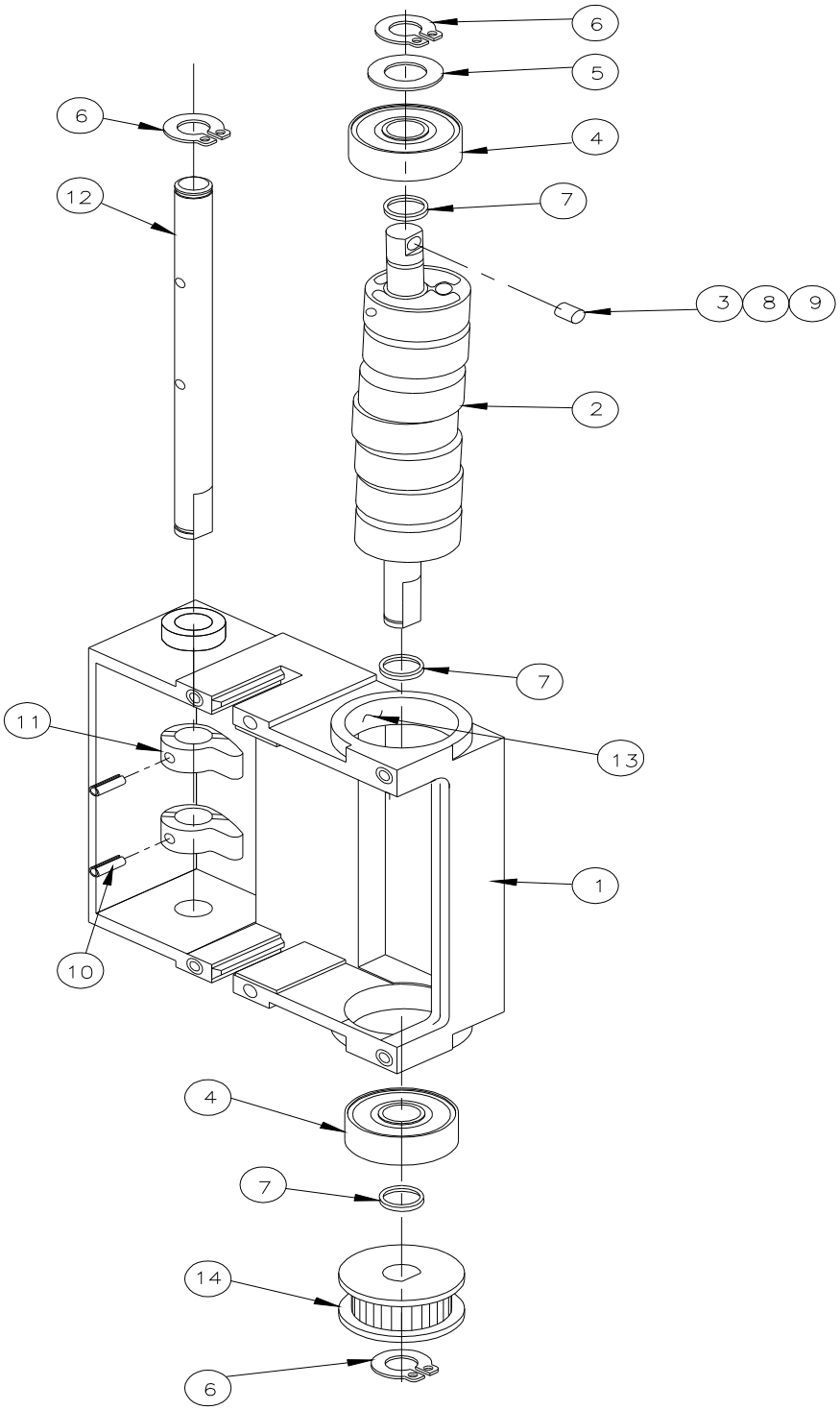
FIGURE 2.9.1 POLE CLAMP ASSEMBLY (DWG 35007 Rev. K)



DETAIL A	
ASSEMBLY NUMBER	RS-232 LABEL P/N
35007	40009
35007F	40009F

ITEM	QTY	P/N	DESCRIPTION
38	AR	85245	LOCTITE, 425 ASSURE
37	1	95036	SET SCREW - 8-32 x 3/8
36			
35	1	40012	LABEL - EQUIPOTENTIALITY
34	1	86340	LABEL - GROUND
33	2	85134	NUT 6MM
32	2	85206	WASHER STAR 6MM
31	1	86690	EXTERNAL GROUND STUD
30	2	85037	SCREW - 8-32 x 1/2
29	1	50025	CORD RETAINER
28	AR	90023	HIGH VACUUM GREASE
27	AR	T106	SANDPAPER - 220 GRIT
26	1	SEE DETAIL A	LABEL - RS-232
25	1	40016	LABEL - CSA
24	1	40038	LABEL - INTERNAL FUSE SPEC.
23	1	40037	LABEL - BATTERY SPEC.
22	AR	90019	LOCTITE 406
21	1	50072	ANTI - TIP ADAPTER
20			
19			
18	AR	90012	ALCOHOL
17	1	40023	POLE CLAMP PAD
16	1	40032	SPACER BATTERY COMP
15	2	86727	SIL-PAD
14	2	95166	SHOULDER WASHER - NYLON
13	5	95018	SCREW 4-40 x 1/4/ BH
12	1	55022	KNOB - POLE CLAMP
11	1	95109	SNAP RING
10	1	95102	WASHER
9	1	50007	SHAFT - DOUBLE, LEAD THD
8	1	95108	WASHER - RED FIBER
7	1	45040	PLUNGER
6	4	95004	SCREW 2-56 x 3/16
5	1	50005	COVER PLATE
4	1	40025	GASKET - COVER PLATE
3	4	95029	SCREW 8-32 x 9/16 CAPTIVE
2	1	60001	ASSEMBLY REGULATOR PCB
1	1	50026	BACK PANEL/POLE CLAMP

BILL OF MATERIALS


6
5
4
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3
8
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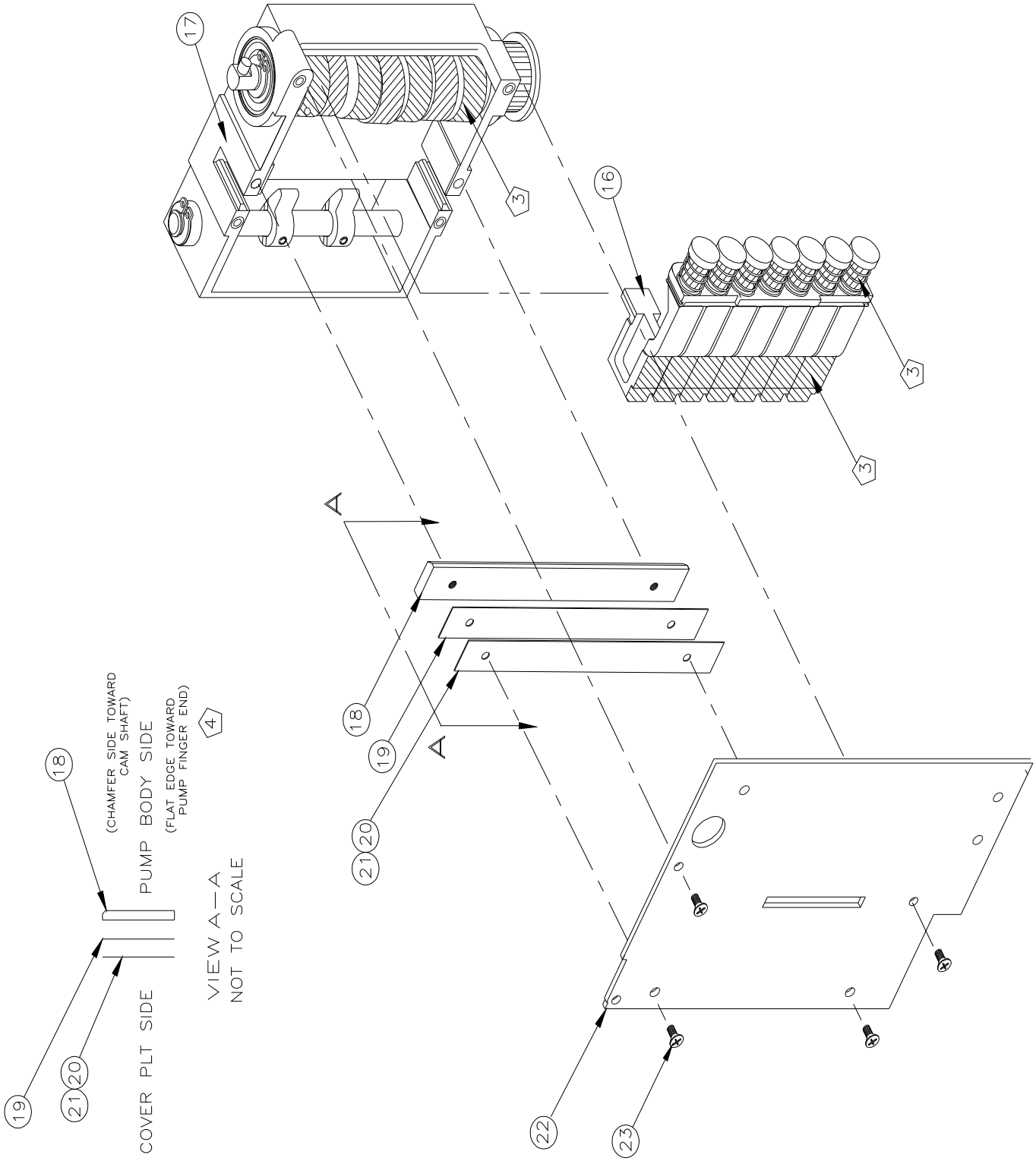
6
12
11
10

FIGURE 2.10.1 PUMP ASSEMBLY (DWG 35005-1 Rev. K)



23	4	95022	SCREW, 4–40 x 3/16 FH
22	1	50015	FACE PLATE
21	OPT	40029–2	MYLAR STICKER, .0075 THK.
20	OPT	40029–1	MYLAR STICKER, .005 THK.
19	OPT	40029	MYLAR STICKER, .010 THK.
18	1	50018	GUIDE BAR
17	1	35005	PUMP BODY SUB ASSEMBLY
16	1	35008	PUMP FINGER ASSEMBLY
15	AR	80514	HIGH VACUUM GREASE
14	1	45042	PULLEY – PUMP
13	AR	85249	ADHESIVE – LOCTITE #406
12	1	50001	SHAFT – LEVER
11	2	50030	ELLIPSE CAM – LEVER SS
10	2	95026	ROLL PIN ø.093 x .500 SS
9	AR	90025	LOCTITE – #712 PRIMER/ACCEL.
8	AR	90005	LOCTITE – #580 BLACK MAX
7	3	70112	SPACER – BRASS CAM SHAFT
6	3	95104	SNAP RING
5	1	95103	WASHER .265 x .500
4	2	55021	BEARING – SHIELDED
3	1	55024–2	MAGNET – .375 LNG
2	1	35006	CAM/SHAFT ASSEMBLY
1	1	45030	PUMP BODY – RAW
ITEM	QTY	P/N	DESCRIPTION

BILL OF MATERIALS

FIGURE 2.11.1 REAR CASE ASSEMBLY (DWG 35003s2 Rev. N)

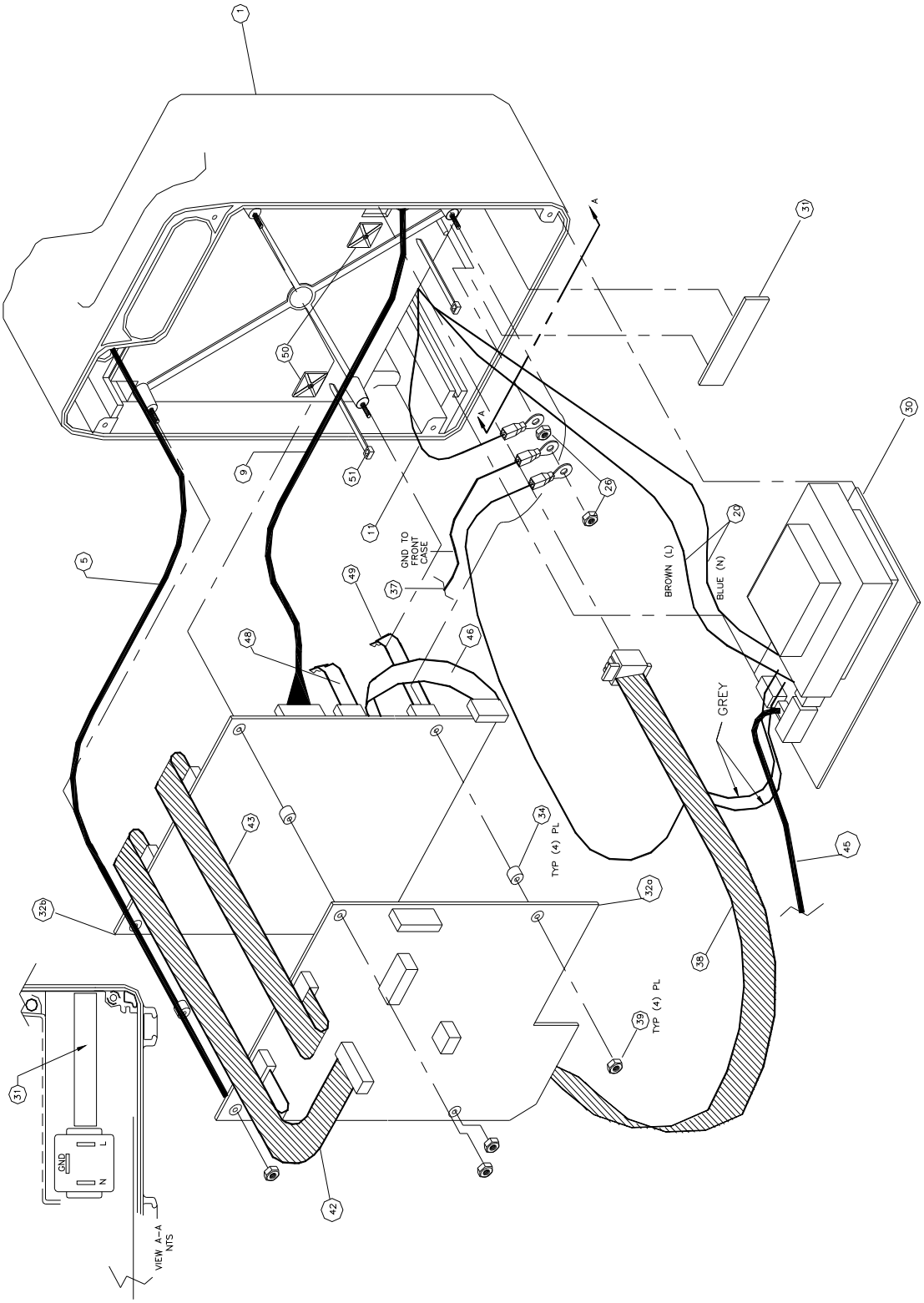
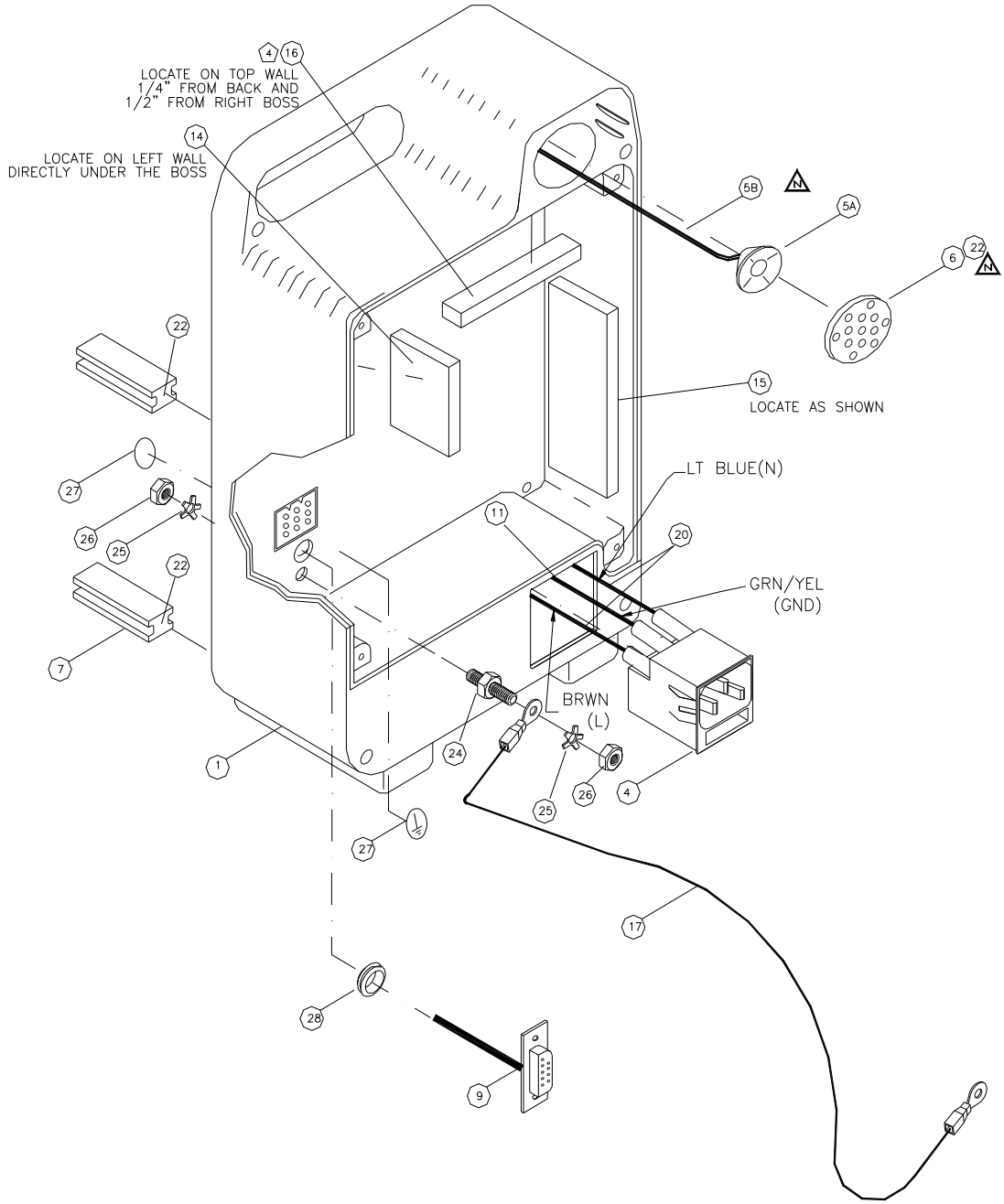


FIGURE 2.11.1 REAR CASE ASSEMBLY (DWG 35003s1 Rev. N)



ITEM	QTY	P/N	DESCRIPTION
51	2	85086	WIRE TIE, .7 M—M
50	2	86484	WIRE HOLD DOWN
49	1	35103	UPSTREAM CABLE
48	1	35101	ROLLER CLAMP HOLDER CABLE
47			
46	1	35038	DOWNSTREAM CABLE
45	1	35021	AC INDICATOR CABLE
44			
43	1	35116	J7 PROCESSOR CABLE
42	1	35113	DISPLAY CABLE W/EXT
41			
40			
39	4	95153	ESNA NUT
38	REF	35022	POWER SUPPLY CABLE
37	1	35026	BONDING WIRE KEYPAD/MTR MNT
36			
35			
34	4	95124	SPACER — PCB
33			
32b	1	60010—1	SENSOR PCBA
32a	1	60010—1	PROCESSOR PCBA
31	1	85011	FOAM PAD, 1/8 x1/2 x2 1/2" L
30	1	35050	TRANSFORMER PCBA S/A
28	1	95130	GROMMET
27	2	86340	LABEL — GROUND SYMBOL
26	4	85254	NUT — 8—32 SMALL PATTERN
25	2	85071	WASHER — #8 EXTERNAL STAR
24	1	95035	ADAPTER, MALE, GROUND
23			
22	1	85081	ADHESIVE, LOCTITE 414
21			
20	REF	35017	LINE HARNESS
19			
18			
17	1	35028	BONDING WIRE—REAR PANEL
16	1	40032—2	FOAM PAD
15	1	40032—3	FOAM PAD
14	1	40032—1	FOAM PAD
13			
12			
11	1	35044	BONDING WIRE — IEC MODULE
10			
9	1	35023	RS232 CABLE
8			
7	2	55018	RUBBER FEET
6	1	45022	SPEAKER CAP
5B	1	35036	SPEAKER CABLE
5A	1	55012	SPEAKER
4	1	55009	LINE IN FILTER
3			
2			
1	1	45020	REAR CASE MOLDED

BILL OF MATERIAL

FIGURE 2.12.1 FRONT CASE ASSEMBLY (DWG 35002s1 Rev. U)

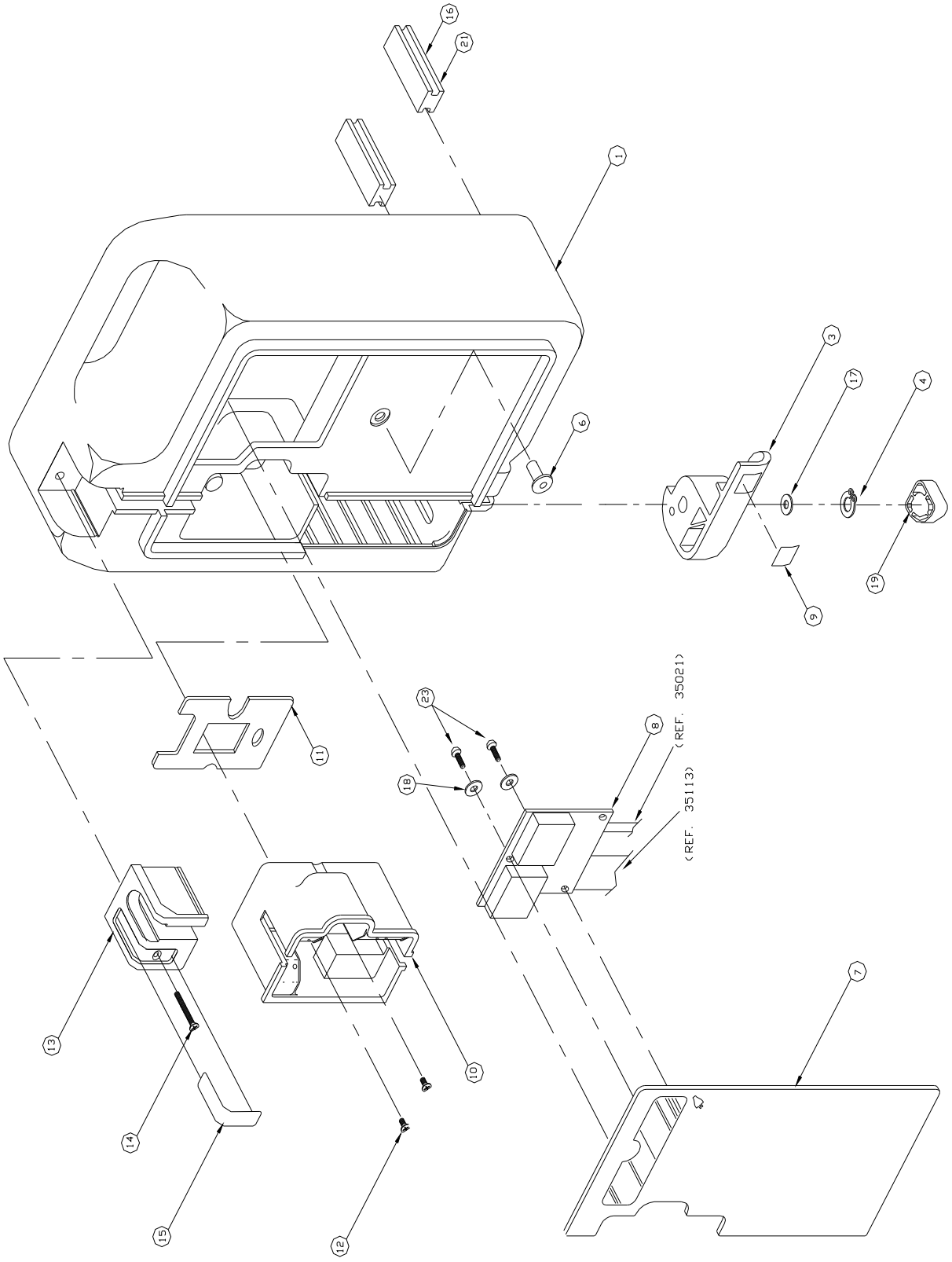


FIGURE 2.12.1 FRONT CASE ASSEMBLY (DWG 35002s2 Rev. U)

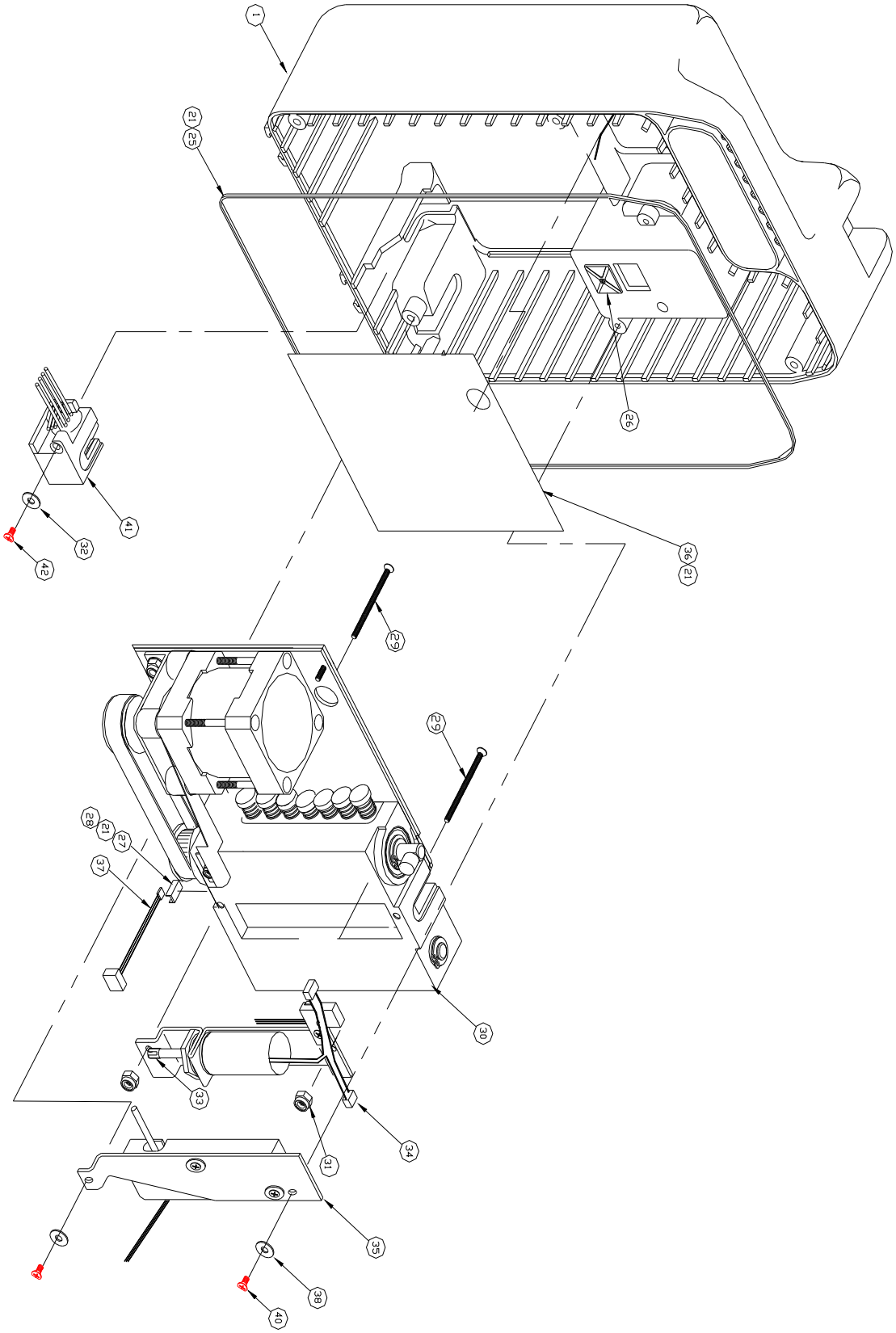
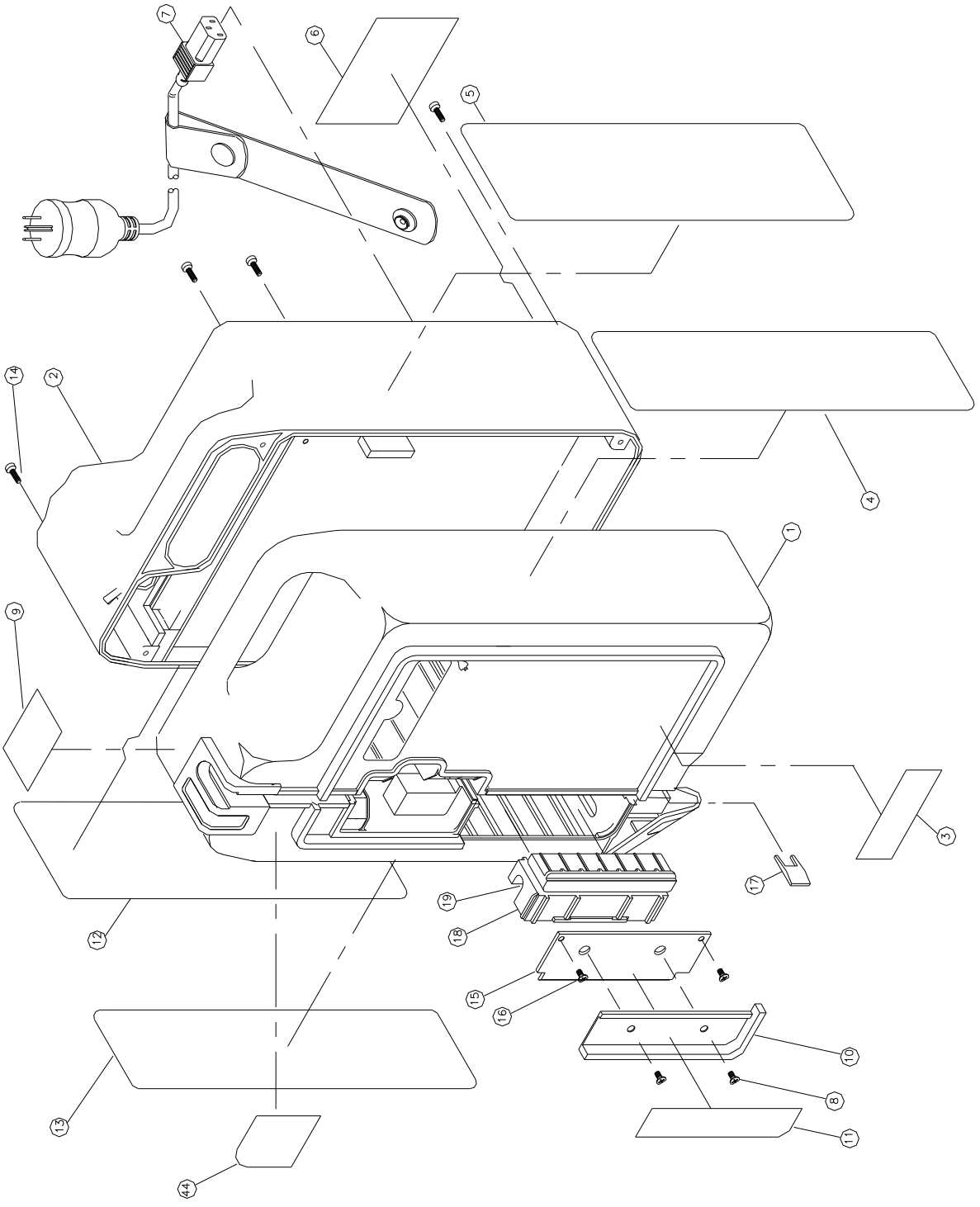


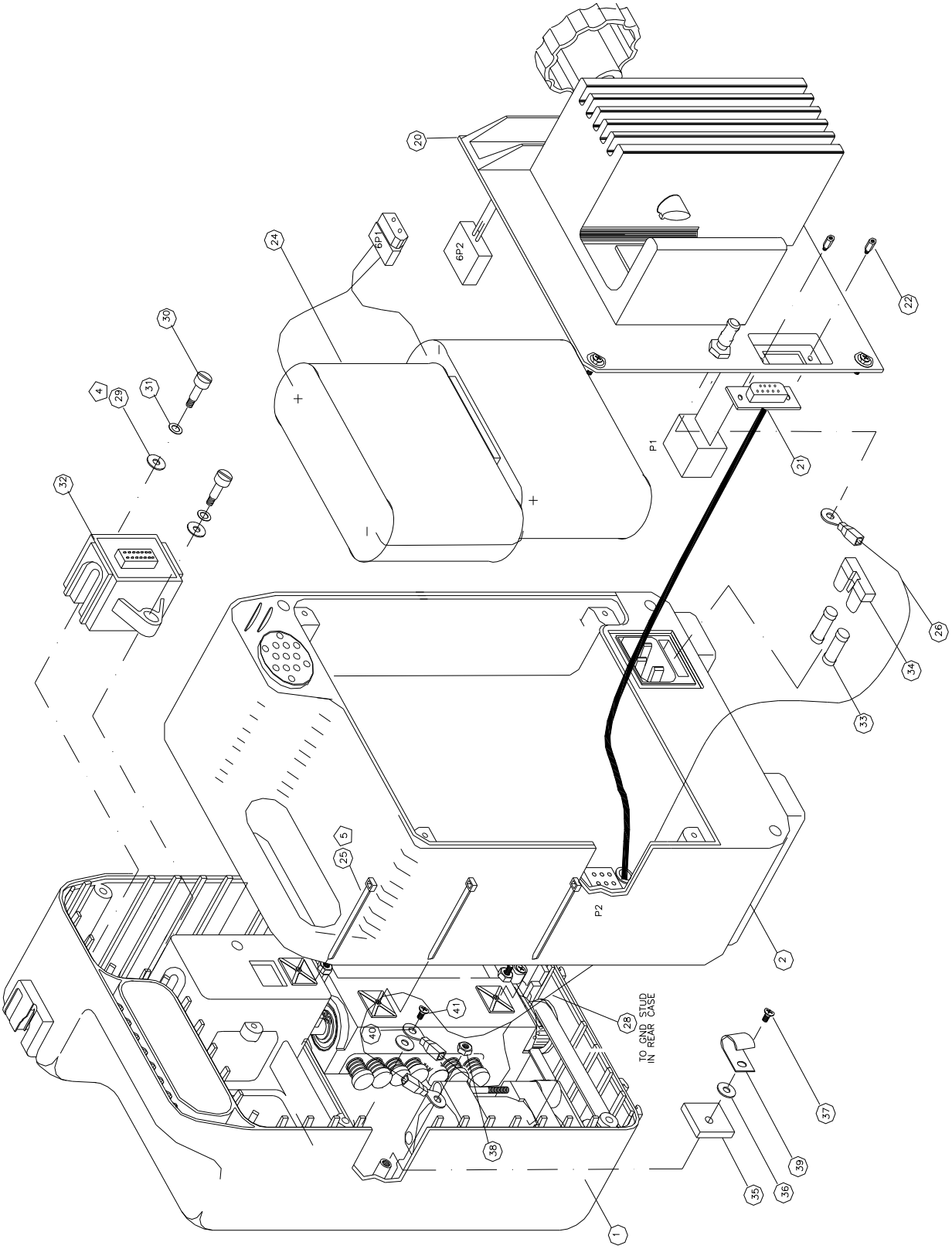
CHART A				
ASSEMBLY NUMBER	ASSEMBLY RC HOLDER	MEMBRANE SWITCH P/N	SYRINGE HLD LABEL P/N	LEVER ID LABEL P/N
35002	35011	40001	40017	40056
35002F	35011F	40001F	40017F	40056F
35002P	35011	40001-1	40017	40056
35002PF	35011F	40001-1F	40017F	40056F

ITEM	QTY	P/N	DESCRIPTION
42	1	95011	SCREW, 4-20 x 7/16" LG, BH
41	1	35012	DOWNSTREAM SENSOR ASM
40	2	95018	SCREW, 4-40 x 1/4"LG, BH
39			
38	2	85068	WASHER, #4 INT TOOTH STAR SS
37	1	35045	CABLE, LEVER OPEN ASM
36	1	40031	GASKET, PUMP BODY/MOTOR ASM
35	1	35009	BOLT HOUSE ASSEMBLY
34	1	35047	SOLENOID ASSEMBLY
33	1	55059-1	SILICONE RUBBER DAMPER
32	1	85067	WASHER, # 4 FLAT .125/.130 x .315 x 22 THK
31	2	95153	NUT, ESNA, 4-40 NYLON INSERT, SS
30	1	35018	PUMP BODY/MOTOR ASM
29	2	85223	SCREW, 4-40 x 1 3/8, FHMS
28	AR	90025	ACCELERATOR, LOCTITE 712
27	1	45055	HALL EFFECT MOUNT
26	1	86484	WIRE HOLD DOWN
25	1	40019	GASKET, CASE
24			
23	2	95018	4-40 x 1/4" BHMS
22			
21	AR	85081	ADHESIVE, LOCTITE 414
20	AR	85088	ALCOHOL
19	1	45048	LEVER CAP
18	2	95119	WASHER NYLON
17	1	95103	WASHER .265 x .500
16	2	55018	RUBBER FEET
15	1	SEE CHART A	LABEL, SYRINGE HOLDER
14	1	85223	4-40 x 1 3/8, FHMS
13	1	45005	SYRINGE HOLDER
12	2	95001	4-40 x 5/16 LNG WHT
11	1	40014	GASKET, R.C.H.
10	1	SEE CHART A	ROLLER CLAMP HOLDER ASM
9	1	SEE CHART A	LABEL, LEVER
8	1	60004	DISPLAY PCB ASM
7	1	SEE CHART A	MEMBRANE SWITCH
6	1	95013	RIVET FASTENER 6-32
5			
4	1	95104	SNAP RING
3	1	35058	LEVER ASSEMBLY
2			
1	1	45001	FRONT CASE

BILL OF MATERIALS

FIGURE 2.13.1 FINAL ASSEMBLY (DWG 35001 Rev. T)




20
6P1
6P2
24
22
30
4
29
31
P1
21
32
26
34
33
5
25
P2
2
41
28
TO GND STUD
IN REAR CASE
40
37
38
39
35
36
1

41	1	1	1	1	1	1	1	1	1	1	1	1	85240	SCREW, 4-40 x 1/4" LG., PHIL, FHMS, SS
40	1	1	1	1	1	1	1	1	1	1	1	1	85073	WASHER, .218" x .120" x .060" THK, NYLON
39	1	1	1	1	1	1	1	1	1	1	1	1	86485	CLIP, WIRE HARNESS
38	1	1	1	1	1	1	1	1	1	1	1	1	85254	NUT, 8-32 HEX SMALL PATERN, SS
37	1	1	1	1	1	1	1	1	1	1	1	1	85033	SCREW, 6-32 x 1/4" LG., TRUSS HEAD SS
36	1	1	1	1	1	1	1	1	1	1	1	1	95122	WASHER, .396x.147x.005 THK
35	1	1	1	1	1	1	1	1	1	1	1	1	40036	BUSHING, FACE PLATE MOUNT
34		REF	REF	REF	REF	REF	REF	REF	REF	REF	REF	REF	55009	IN-LINE FILTER FUSE COVER
	2	2	2	2	2	2	2	2	2	2	2	2	25307	FUSE, 500mA, 250V (DOMESTIC)
33	—	—	—	—	—	—	—	—	—	—	—	—	25311	FUSE, 250mA, 250V (EXPORT)
	—	—	1	1	—	—	—	—	—	—	—	—	35010-3	UPSTREAM SENSOR ASM w/THERMISTER, MCG
32	1	1	—	—	1	1	1	1	1	1	1	1	35010-2	UPSTREAM SENSOR ASM w/THERM., ABB/ BAX
31	2	2	2	2	2	2	2	2	2	2	2	2	85149	WASHER, # 5 CURVED SS
30	2	2	2	2	2	2	2	2	2	2	2	2	95030	SCREW, 1.313, SHLDR
29	1	1	1	1	1	1	1	1	1	1	1	1	95113	WASHER, .400/.425x.175/.180x.010 THK
28	REF	REF	REF	REF	REF	REF	REF	REF	REF	REF	REF	REF	35026	BONDING WIRE, KEYPAD/MOTOR MOUNT
27	REF	REF	REF	REF	REF	REF	REF	REF	REF	REF	REF	REF	35021	CABLE, AC INDICATOR
26	REF	REF	REF	REF	REF	REF	REF	REF	REF	REF	REF	REF	35028	BONDING WIRE, REAR PANEL
25	11	11	11	11	11	11	11	11	11	11	11	11	85086	WIRE TIE, .7 M-M
24	1	1	1	1	1	1	1	1	1	1	1	1	55002-1	BATTERY ASSEMBLY, HAWKER
23	1	1	1	1	1	1	1	1	1	1	1	1	35112	CABLE, KEYPAD
22	2	2	2	2	2	2	2	2	2	2	2	2	95020	STANDOFF, 4-40 x 3/16"
21	REF	REF	REF	REF	REF	REF	REF	REF	REF	REF	REF	REF	35023	CABLE, RS-232
	—	—	—	—	—	—	1	1	—	—	—	—	35007F	BACK PANEL / POLE CLAMP ASSEMBLY, FRENCH
20	1	1	1	1	1	1	—	—	1	1	1	1	35007	BACK PANEL / POLE CLAMP ASSEMBLY
19	A/R	A/R	A/R	A/R	A/R	A/R	A/R	A/R	A/R	A/R	A/R	A/R	80154	GREASE, HIGH VACUUM
	1	1	—	—	—	—	1	1	1	1	1	1	35019-3	PRESSURE PLATE ASM, ABBOTT
	—	—	—	—	1	1	—	—	—	—	—	—	35019-2	PRESSURE PLATE ASM, BAXTER
18	—	—	1	1	—	—	—	—	—	—	—	—	35019-1	PRESSURE PLATE ASM, MCG
	1	1	—	—	1	1	1	1	1	1	1	1	45052-2	RIB INSERT, DOWNSTREAM, ABB/BAX
17	—	—	1	1	—	—	—	—	—	—	—	—	45052-1	RIB INSERT, DOWNSTREAM, MCG/BRA
16	2	2	2	2	2	2	2	2	2	2	2	2	85218	SCREW, # 2-56 x 1/4 LG, FHMS
15	1	1	1	1	1	1	1	1	1	1	1	1	50014	PLATE, COVER, PRESSURE PLATE
14	4	4	4	4	4	4	4	4	4	4	4	4	95027	SCREW, # 6-32 x 3/4 LG, SCKT HD
	—	—	—	—	—	—	1	1	—	—	—	—	40008F	LABEL, CASE CAUTIONS, FRENCH
13	1	1	1	1	1	1	—	—	—	1	—	1	40008	LABEL, CASE CAUTIONS
	—	—	—	—	—	—	1	1	—	—	—	—	40007F	LABEL, CASE OPTIONS, FRENCH
12	1	1	1	1	1	1	—	—	1	1	1	1	40007	LABEL, CASE OPTIONS
	—	—	—	—	—	—	1	1	—	—	—	—	40011F	LABEL, ACCESS PANEL, FRENCH
11	1	1	1	1	1	1	—	—	1	1	1	1	40011-1	LABEL, ACCESS PANEL
10	1	1	1	1	1	1	1	1	1	1	1	1	45002	ACCESS PANEL
	—	—	—	—	—	—	1	1	—	—	—	—	40010F	LABEL, TUBE ID, ABBOTT, FRENCH
	1	1	—	—	—	—	—	—	—	—	—	—	40010-4	LABEL, TUBE ID, SECURUS AN
	—	—	1	1	—	—	—	—	—	—	—	—	40010-3	LABEL, TUBE ID, McGAW
	—	—	—	—	—	—	—	—	1	1	1	1	40010-2	LABEL, TUBE ID, ABBOTT
9	—	—	—	—	1	1	—	—	—	—	—	—	40010-1	LABEL, TUBE ID, BAXTER
8	2	2	2	2	2	2	2	2	2	2	2	2	85218	SCREW, # 2-56 x 1/4 LG, FHMS
7	1	1	1	1	1	1	1	1	1	1	1	1	35014	CORD SET ASSEMBLY
	—	—	—	—	—	—	—	—	1	—	1	—	40015A	LABEL, ELEC CAUT. /SER #, DOM., ABB. ENG.
	—	—	—	—	—	—	1	1	—	—	—	—	40015F	LABEL, ELEC CAUT. /SER #, DOM., FRENCH
6	1	1	1	1	1	1	—	—	—	1	—	1	40015	LABEL, ELEC CAUT. /SER #, DOM.
	—	—	—	—	—	—	1	1	—	—	—	—	40006F	LABEL, CASE ALARMS, FRENCH
5	1	1	1	1	1	1	—	—	1	1	1	1	40006	LABEL, CASE ALARMS
	—	—	—	—	—	—	1	1	—	—	—	—	40005F	LABEL, CASE INSTRUCTIONS, FRENCH
4	1	1	1	1	1	1	—	—	1	1	1	1	40005	LABEL, CASE INSTRUCTIONS
3	—	—	—	—	—	—	—	—	1	—	1	—	40082	ABBOTT OVERLAY (ABBOTT DIST. PUMPS ONLY)
2	1	1	1	1	1	1	1	1	1	1	1	1	35003	REAR CASE ASSEMBLY
	—	—	—	—	—	—	1	—	—	—	—	—	35002PF	FRONT CASE ASSEMBLY, PLUS FRENCH
	—	—	—	—	—	—	—	1	—	—	—	—	35002F	FRONT CASE ASSEMBLY, FRENCH
	1	—	1	—	1	—	—	—	1	1	—	—	35002P	FRONT CASE ASSEMBLY, PLUS
1	—	1	—	1	—	1	—	—	—	—	1	1	35002	FRONT CASE ASSEMBLY
ITEM	QTY												P/N	DESCRIPTION
FINAL ASSEMBLY WORK ORDER	35001SAN(XXX)P	35001SAN(XXX)	35001MCG(XXX)P	35001MCG(XXX)	35001BAX(XXX)P	35001BAX(XXX)	35001ABB(XXX)PF	35001ABB(XXX)F	35001ABB(XXX)PE	35001ABB(XXX)P	35001ABB(XXX)E	35001ABB(XXX)	ABB – ABBOTT BAX – BAXTER MCG – McGAW BRN – BRAUN SAN – SECURUS AN E – ENGLISH P – PLUS F – FRENCH	
BILL OF MATERIALS														

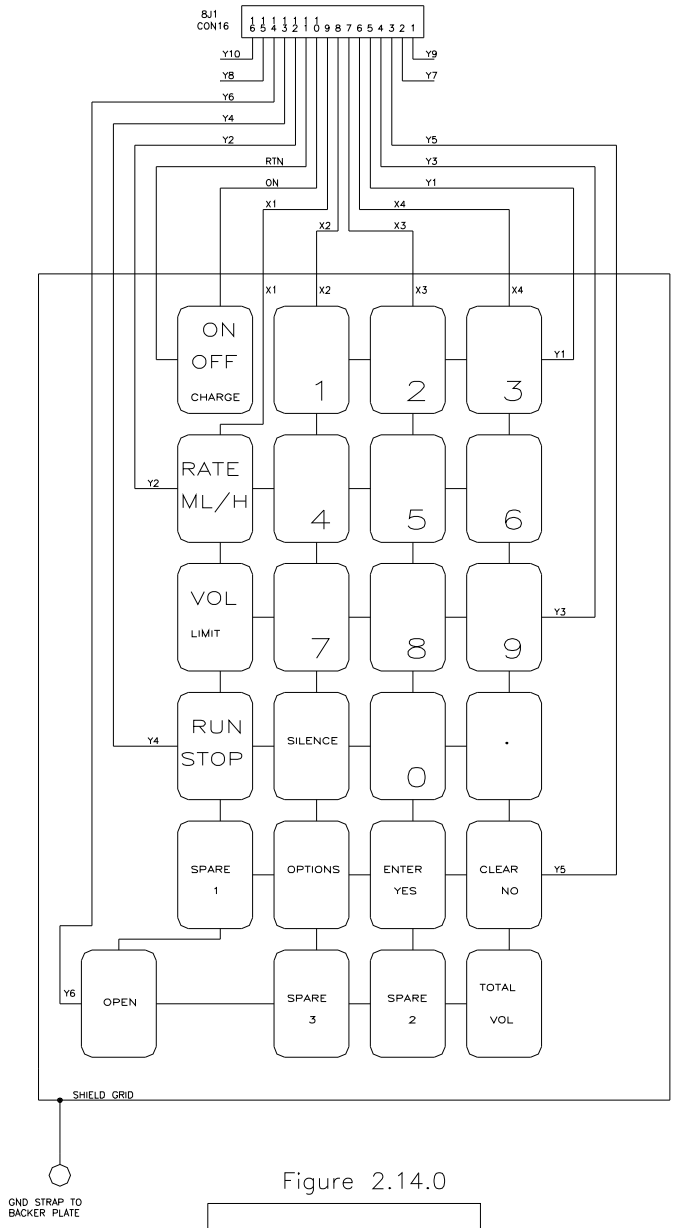


Figure 2.14.0

KEYBOARD
SCHEMATIC

FILE NAME: 8000 OPS MANUAL.dwg

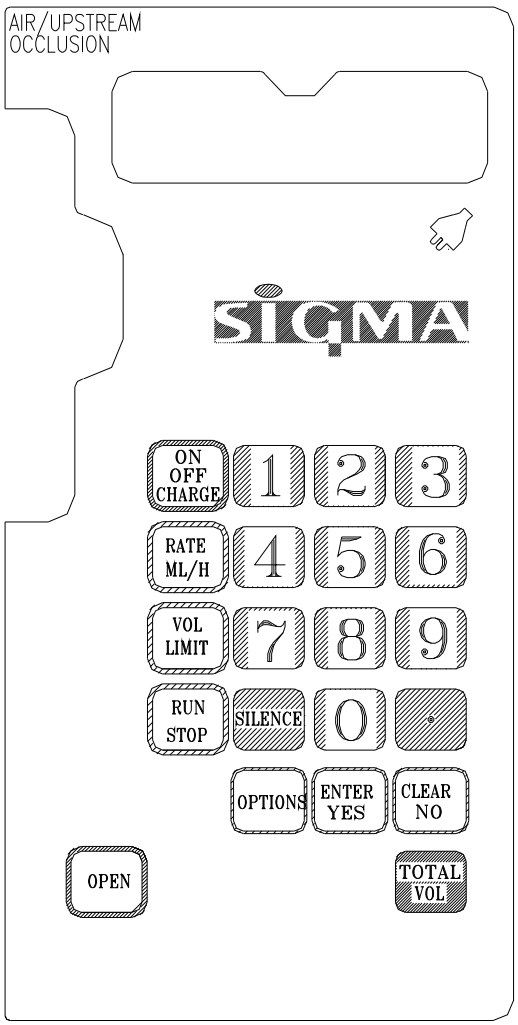


Figure 2.14.1

8000
KEYBOARD
GRAPHICS

FILE NAME: 8000 OPS MANUAL.dwg

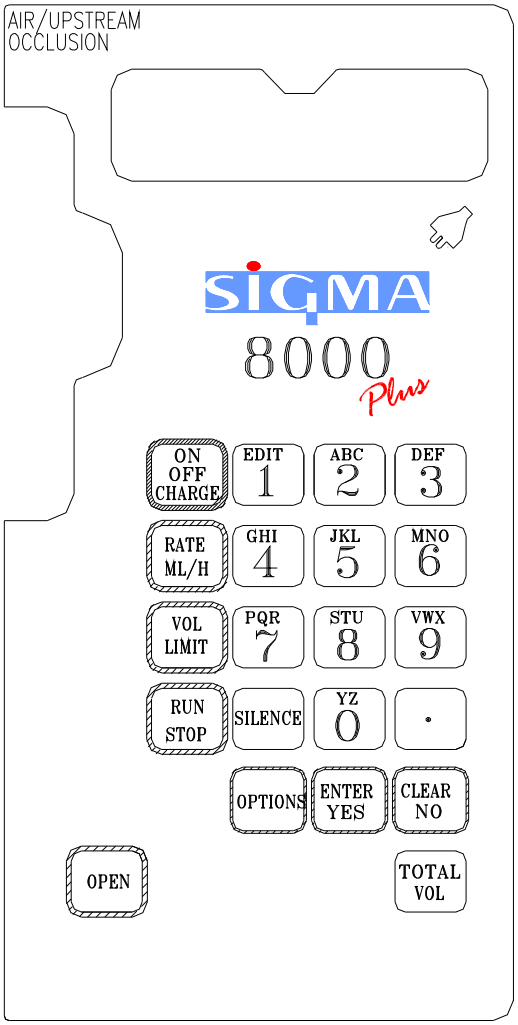
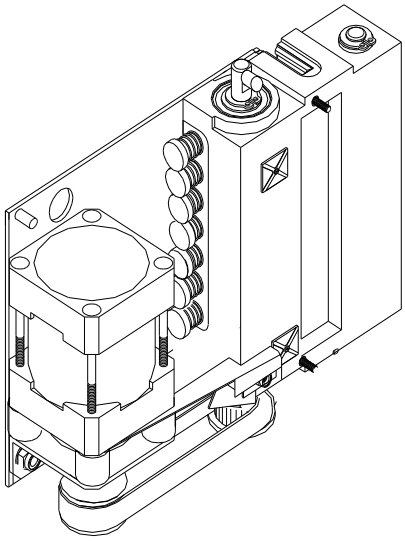
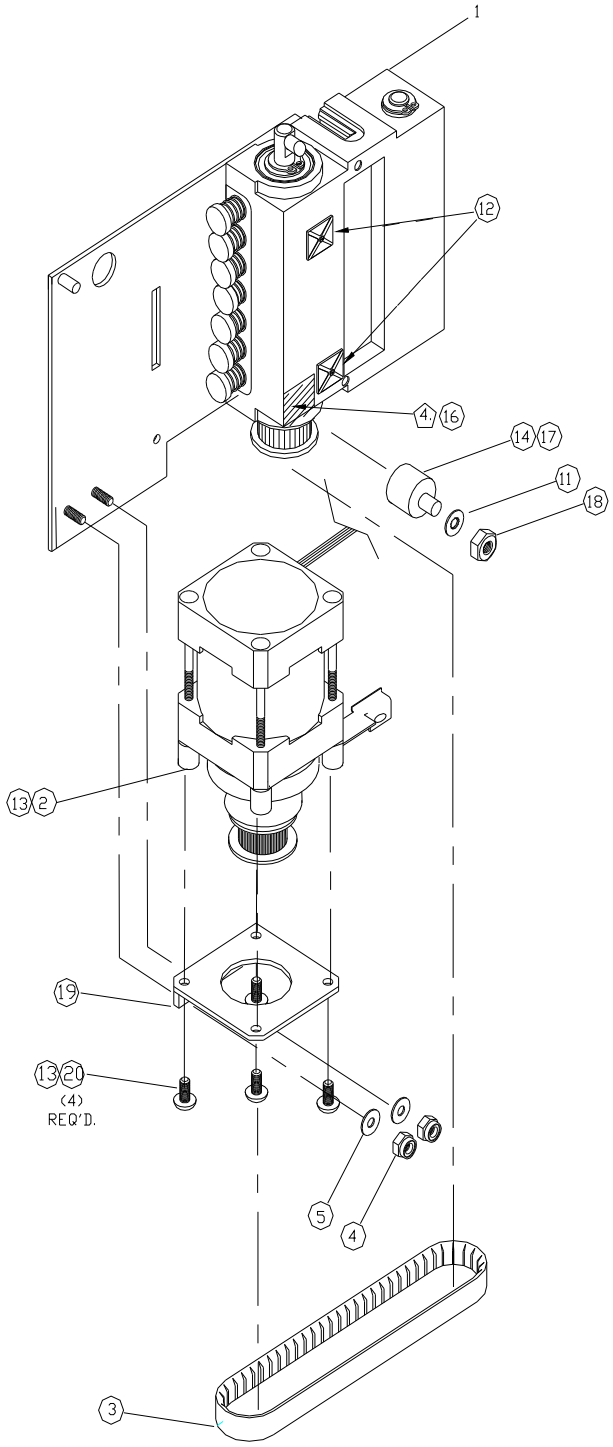


Figure 2.14.2

8000 *Plus*
KEYBOARD
GRAPHICS

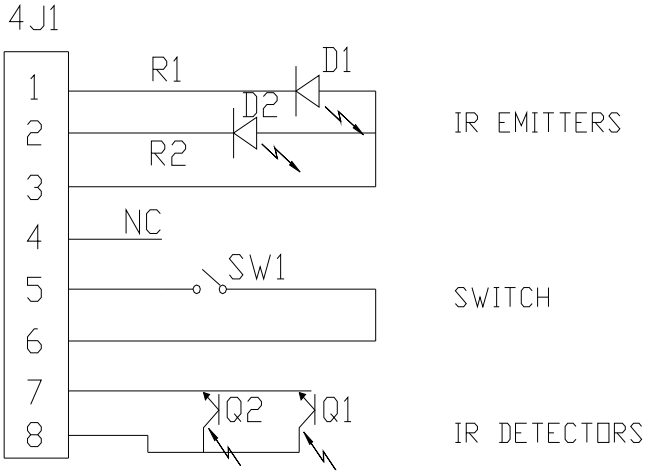
FILE NAME: 8000 OPS MANUAL.dwg

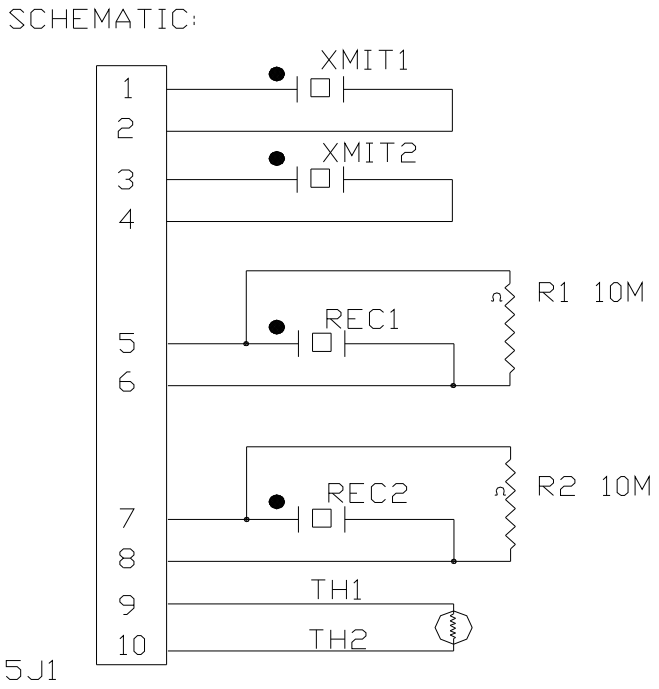



1
12
4
16
14
17
11
18
13
2
19
13
20
(4)
REQ'D.
5
4
3

ITEM	QTY	P/N	DESCRIPTION
20	4	85033	SCREW - 6-32 x 1/4" PHIL TRUSS
19	1	50017	MOTOR MOUNT
18	1	85254	HEX NUT 8-32 SMALL PATTERN
17	AR	90029	PRIMER - LOCTITE 770
16	AR	85081	ADHESIVE - 414
15			
14	1	95019	STUD MOUNT STABILIZER ARM
13	AR	85203	ADHESIVE - LOCTITE #222
12	2	86484	WIRE HOLD DOWN
11	1	95123	#8 INTERNAL TOOTHSTAR LOCKWASHER
5	2	85067	WASHER #4 FLAT
4	2	95153	ESNA NUT
3	1	55020	MOTOR BELT
2	1	35004	MOTOR ASSEMBLY
1	1	35005-1	PUMP SUB ASSEMBLY

FIGURE 2.16.1 ROLLER CLAMP PCB SCHEMATIC (DWG 60018 Rev. E)




SCHEMATIC:
XMIT1
1
2
XMIT2
3
4
R1 10M
REC1
5
6
R2 10M
REC2
7
8
TH1
9
TH2
10
5J1

SERVICE MANUAL
SIGMA INTERNATIONAL
MODEL 8000 & 8000 *Plus*
INFUSION PUMPS
SECTION 3

SECTION 3 THEORY OF OPERATION

3.1 MECHANICAL COMPONENTS

- 3.1.1 CASE
- 3.1.2 BACK PANEL/POLE CLAMP ASSEMBLY
- 3.1.3 TUBE CHANNEL
  - 3.1.3.1 AIR/UPSTREAM OCCLUSION SENSOR
    - 3.1.3.1.1 UPSTREAM AIR/OCCLUSION DETECTION
  - 3.1.3.2 ROLLER CLAMP HOLDER
    - 3.1.3.2.1 UNCONTROLLED FLOW PROTECTION
    - 3.1.3.2.2 ROLLER CLAMP SENSING
  - 3.1.3.3 PUMP ASSEMBLY
    - 3.1.3.3.1 PERISTALTIC PUMP FINGERS AND PRESSURE PLATE
  - 3.1.3.4 DOWNSTREAM OCCLUSION SENSOR
    - 3.1.3.4.1 DOWNSTREAM OCCLUSION SENSING
  - 3.1.3.5 PRESSURE PLATE RELEASE LEVER
- 3.1.4 STEPPER MOTOR AND DRIVE BELT
  - 3.1.4.1 MOTOR
  - 3.1.4.2 MOTOR DRIVER
  - 3.1.4.3 STEPPER MOTOR CONTROL

3.2 ELECTRONIC COMPONENTS

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  - 3.2.1.1 BLOCK DIAGRAM AND CABLE DIAGRAM
- 3.2.2 TRANSFORMER PCB/AC LINE CIRCUIT
  - 3.2.2.1 LINE CORD
    - 3.2.2.1.1 LINE CORD AND INPUT VOLTAGE SELECTOR
  - 3.2.2.2 AC INLET MODULE, FUSES
  - 3.2.2.3 POWER TRANSFORMER
  - 3.2.2.4 SECONDARY VOLTAGE AND POWER INDICATOR
- 3.2.3 REGULATOR PCB/BATTERY CIRCUIT
  - 3.2.3.1 RECTIFIER, FILTER, REGULATOR
  - 3.2.3.2 LOGIC VOLTAGE SUPPLY AND SWITCH
  - 3.2.3.3 BATTERY CHARGER
  - 3.2.3.4 BATTERY PACK
  - 3.2.3.5 REGULATOR PCB
- 3.2.4 DISPLAY PCB/AUXILIARY BUS
  - 3.2.4.1 DISPLAY PCB
  - 3.2.4.2 DISPLAY/AUXILIARY BUS INTERFACE
  - 3.2.4.3 LED DISPLAYS
- 3.2.5 SENSOR PCB
- 3.2.6 PROCESSOR PCB
  - 3.2.6.1 MICROPROCESSOR
  - 3.2.6.2 POWER SWITCHING CONTROL
  - 3.2.6.3 STATIC RAM AND PROGRAM PROM
  - 3.2.6.4 ELECTRICALLY ERASABLE PROM
  - 3.2.6.5 RTC CLOCK AND SUPERVISOR CIRCUIT
  - 3.2.6.6 ANALOG INPUT CHANNELS
  - 3.2.6.7 PUMP TEMPERATURE MONITOR
  - 3.2.6.8 SPEAKER DRIVER/VOLUME CONTROL
    - 3.2.6.8.1 SPEAKER
  - 3.2.6.9 DISPLAY/AUXILIARY INTERFACE

3.2.7 KEYBOARD
3.2.7.1 KEYBOARD INTERFACE
3.2.8 TEST PORT, SHAFT SENSOR, FLOW SENSOR, LEVER LOCK CONTROL
3.2.9 BACK PANEL/SERIAL INTERFACE CONNECTOR
3.2.9.1 FLOW SENSOR AND INTERFACE
3.2.9.2 NURSE CALL
3.2.9.3 SERIAL COMMUNICATION INTERFACE

3.0 MODEL 8000 INFUSION PUMP THEORY OF OPERATION

3.1 MECHANICAL COMPONENTS

3.1.1 CASE

The Model 8000 Case is a two-piece plastic molding, providing mounting and protection for all of the other components in the Pump. The plastic material chosen for the case provides high strength and a UL Flame Spread Rating of 94V-O.

Refer to Figure 2.0.1 and Figure 2.0.2 for the front and rear Views of the case, respectively.

Case assembly details are contained in:

- Figure 2.11.1, Assembly Drawing, Rear Case
- Table 2.11.2, Bill of Material, Rear Case
- Figure 2.12.1, Assembly Drawing, Front Case
- Table 2.12.2, Bill of Material, Front Case
- Figure 2.13.1, Assembly Drawing, Final /Labels
- Table 2.13.2, Bill of Material, Final/Labels

3.1.2 BACK PANEL/POLE CLAMP ASSEMBLY

The Back Panel/Pole Clamp assembly is a one-piece aluminum die casting, providing the facility for mounting the Model 8000 Pump on a standard IV pole. The Pole Clamp will accept round poles with diameters between 0.5 and 1.0 inches (12.7 – 25.4 mm), and is secured to the pole by a screw mechanism and hand knob. It acts as a removable cover for access to the battery and is a heat dissipation surface allowing the internal case temperature to be kept below the 105 degree F temperature desirable for reliability. It also provides means for mounting of the PCA syringe holder assembly.

The Back Panel/Pole Clamp Assembly is described in Figure 2.9.1 and the accompanying Bill of Material, Table 2.9.2.

3.1.3 TUBE CHANNEL

The Tube Channel is a slot in the front of the Model 8000 Volumetric Infusion Pump, which holds and acts upon the tubing of the IV set.

Arrayed along the Tube Channel from top to bottom are all of the devices used to monitor and control fluid delivery through the tubing. These include the peristaltic pump assembly and a variety of sensors and mechanical devices essential to operation.

The devices in the Tube Channel are described in the following sub-sections in order from the top of the Tube Channel to the bottom, which is the direction of fluid flow.

3.1.3.1 AIR/UPSTREAM OCCLUSION SENSOR

See Schematic, Figure 2.17.0, Assembly.

The Air\Upstream Occlusion Sensor is comprised of a molded plastic housing incorporating two (2) pairs of ultrasonic transducers. The housing is designed to efficiently couple the signals from the transmitters through the I.V. set, and its contents, back to the receiving transducers.

The tubing in the Tube Channel passes through the Air/Upstream Occlusion Sensor before it reaches the Pump Mechanism. Air bubbles in the fluid are sensed, and if of sufficient size pumping will stop, an alarm will sound and a message will be displayed.

Air bubbles are sensed ultrasonically, by measuring characteristics of the sound waves that travel across the diameter of the tubing. Two sensors are spaced 0.5 inch apart along the length of the tubing, and are used simultaneously to sense bubbles, giving better freedom from false alarms. An air bubble greater than 1 inch (25.4 mm) long, or approximately 100 to 150 microliters in volume, stops the pump and results in an alarm and message display, over the entire range of delivery rates. An equivalent single volume of micro-bubbles or foam in the fluid path is interpreted as a continuous air bubble.

Upstream Occlusions are detected by monitoring the loss in signal strength across both of the sensors. A loss of signal results from the loss of contact pressure between the tube and the sensors due to the negative pressure build up internal to the tube during an upstream occlusion.

3.1.3.1.1 Upstream Air/Occlusion Detection

Upstream air and pressure are measured by two ultrasonic transmit/ receive transducer pairs. The two pairs are spaced 0.5 inch apart along the length of the tube channel, allowing the presence of a bubble of this length to be determined.

Air vs. fluid in the tubing is determined by changes in sound transfer characteristics across the tube diameter, indicated by changes in received signal phase and amplitude. A pressure change within the tubing will be reflected by change in the amplitude of the received signal.

Multiple calibration values must be entered to allow for operation of the sensors. There is a frequency setting provided for each of the two transducer pairs, one for pair 1 (upper) and one for pair 2 (lower). Also an air trip threshold and fluid calibration value is provided for each pair. There are calibration values representing relative sensor drive levels, baseline signal levels and other parameters required for overall sensor operation.

The frequency selection is written into the Frequency Register Latch, U31 or U59, from the Aux Bus. The sensor control and drive level are written to U33 in similar fashion.

The frequency value is applied to the "divide by n" input of the respective phase locked loop (PLL), U34 or U57, and causes the voltage controlled oscillator (VCO) to shift until the PLL locks. The VCO runs at twice the transmit frequency. The phase reference stage, U36, divides the VCO frequency by two, and produces a transmit phase reference, whose phase is constant. The reference stage also produces a demod phase reference which may be the same as the transmit phase (0 degrees) or 90 degrees out of phase (90 degrees).

The transmit phase signal excites whichever transmit transducer is selected by turning on its driver (U38 or U39). The final drive stage U65 is powered from the adjustable drive level power supply and drives the transmitting transducer. The demod phase is applied to the reference input of the synchronous demodulator, U40. The level of either 0 degree or 90 degree output from the receive transducer may then be read at Analog input 0, for pair 1, or Analog input 4, for pair 2.

3.1.3.2. ROLLER CLAMP HOLDER
See Schematic, Figure 2.16.0.

The Roller Clamp Holder is a molded plastic housing designed to retain the roller clamp in the pump and house the sensors needed to monitor the presence of the roller clamp and the position of the clamp's roller wheel. The holder is an interchangeable block allowing users the flexibility of using IV sets of various manufacturers, whose roller clamps are of differing sizes.

3.1.3.2.1. Uncontrolled Flow Protection

To install an I.V. set into the Model 8000 Infusion Pump, the roller clamp on the set must first be installed in the Roller Clamp Holder, and the roller must be placed in the closed position. This guarantees that no uncontrolled gravity flow can go undetected prior to the pump being started. The roller must likewise be closed before the tubing is removed from the pump. This assures that no uncontrolled flow is possible during I.V. set removal.

The Tube Channel is locked closed on an installed IV set until the roller clamp is placed in the closed position. This system assures that either a pump finger or a closed roller clamp occludes the tubing to prevent uncontrolled gravity flow through the infusion set. The pump is not allowed to start unless the roller clamp is in the open position, assuring proper fluid delivery.

Three conditions must be met to allow the Tube Channel to be safely opened for unloading or re-priming the IV set, without danger of accidental uncontrolled gravity flow. First, the roller clamp wheel must be closed. Second, the lever locking mechanism must be unlocked. Note in some instances the "OPEN" key on the Keypad must be pressed to do so. Third, the Pressure Plate Release Lever must be pulled open to release the tubing. At this time the IV set may be safely removed from the Tube Channel or the roller clamp may be opened to re-prime the tubing intentionally, under operator supervision.

3.1.3.2.2. Roller Clamp Sensing

Sensors monitor the presence of the clamp and the position of the roller. The presence of the Roller clamp is detected by a switch contact closure. Roller position is sensed with two Infrared Emitter/Detector pairs, one pair at both the open position and the closed position of the roller wheel.

The LED emitter current is chopped at 16.384 kHz to distinguish the infrared beam from room light. The phototransistor IR detector drives a tone detection circuit tuned to the chopping frequency, which changes the output state when the beam is broken.

The three IR LED emitters are driven singly by sections of U27, a high-current tri-state buffer, whose signal inputs are connected to a 16.384 kHz signal divided from the processor clock. The enable inputs for U27 are decoded from two Processor output lines by U22A. The program selects one LED and then monitors the CLAMP O/S output of tone detector U29.

The roller-closed state is determined reflectively, so the CLAMP O/S signal will be low to indicate the presence of the syringe or roller. Roller open breaks the beam, producing CLAMP O/S high to indicate roller presence.

The tone detector is tuned to twice the chopping frequency, or 32.768 kHz, to allow its phase detector to work.

3.1.3.3 PUMP ASSEMBLY

The Model 8000 Volumetric Infusion Pump utilizes a linear peristaltic pumping mechanism. Pumping action is effected by inserting the tubing of an IV set into the Tube Channel and closing the pressure plate on the tubing. The pressure plate maintains the tubing in close contact with the peristaltic pump fingers, allowing the progressive tubing occlusion necessary to the pumping action.

The pumping mechanism assembly is described by figure 2.10.1, and Table 2.10.2 the accompanying Bill of Material.

3.1.3.3.1 Peristaltic Pump Fingers and Pressure Plate

When the tubing is loaded in the peristaltic pumping mechanism, a pressure plate forces the tubing into contact with the tips of the pump fingers. The fingers move sequentially toward the pressure plate, progressively compressing the tubing into occlusion, and forcing the trapped fluid downward. As the last (bottom) finger finishes its compression cycle and begins to retract, the first finger has reached occlusion trapping the next quantity of fluid and starting the next pumping cycle. Flow is effectively continuous.

The sequential motion of the fingers is controlled by a camshaft comprised of seven eccentric cams; each offset rotationally from its neighbors by 1/6 of a revolution.

3.1.3.4 DOWNSTREAM OCCLUSION SENSOR

Downstream occlusion is detected by measuring fluid pressure for a rising pressure trend during pumping, indicating blockage below the pump. If the pressure rises, a downstream occlusion alarm message is displayed, and pumping is suspended.

3.1.3.4.1 Downstream Occlusion Sensing

Internal tubing pressure is sensed below the pumping area of the Tube Channel. If the pressure between the pump and the patient catheter is found to be rising, an appropriate occlusion alarm message is displayed, and an alarm sounded, alerting the user to total obstruction of the fluid path.

The Pump stops and remains stopped, until the cause of the occlusion is removed and the measured pressure is reduced, allowing the delivery to resume automatically.

Downstream pressure is monitored by the Downstream Pressure Transducer, which is a piezo resistive bridge transducer. The transducer is excited with a DC reference of 4.0 volts (U42A). A differential amplifier with a gain of 260 (U42B), boosts the signal level of the transducer, and feeds the signal to Analog input 2 of the Processor.

3.1.3.5 PRESSURE PLATE RELEASE LEVER

The Pressure Plate Release Lever is pulled open to move the pressure plate away from the pump fingers, allowing tubing to be installed in, or removed from, the Tube Channel. The roller clamp must be installed and in its closed position to allow the Lever to be opened, for

removal of the tubing, otherwise, the Lever remains locked and closed at all times when the tubing is sensed in the pump.

3.1.4 STEPPER MOTOR AND DRIVE BELT

See Assembly, Figure 2.7.1, Bill of Material, Table 2.7.2, Assembly, Figure 2.15.1 and Bill of Material, Table 2.15.2.

The pump assembly camshaft is rotated by a Stepper Motor, through a cogged drive belt and cogged pulleys. The Motor allows the camshaft to be rotated throughout the rate range, by increments of 260 motor steps per pump revolution or multiples thereof. Because the motor step rate is derived by the Processor from its crystal controlled clock, the motor rotation rate is constant to near the error of the crystal. Error is less than +/- 0.1% for all sources of error.

3.1.4.1 MOTOR

The Motor is a two-phase, 1.8 degree stepper motor. It is coupled to the pumping mechanism through a glass-reinforced timing belt and cogged pulleys. The pulley drive ratio is 1.3: 1, thereby making the motor make 260 steps (1.3 revolutions) per one revolution of the pump.

3.1.4.2 MOTOR DRIVER

The Driver Circuit for the Motor is located on the Processor Board. Constant current phase drive for the motor coils is provided by a switched-mode, full-bridge motor drive circuit.

3.1.4.3 STEPPER MOTOR CONTROL

The Stepper Motor Control consists of two functions contained in two IC packages. U9 is a dual, seven-bit plus sign, Digital-to-Analog converter, which translates data from the system bus to two analog voltages. The analog voltages determine the motor phase current produced by the pulse width modulated current limiters in the dual motor driver, U8. Sign bits from the A/D determine the polarity of the motor current.

Motor rotation and torque are determined solely by the sequence and amplitude of the voltages written by the Processor to the D/A converter of the control IC. If the Processor fails, the motor stops.

3.2 ELECTRONIC COMPONENTS

3.2.1 FUNCTIONAL BLOCKS

3.2.1.0 BLOCK DIAGRAM AND CABLING DIAGRAM

A Block Diagram showing a simplified interconnection of all of the Functional Blocks which make up the Model 8000 Volumetric Infusion Pump is found in Figure 2.1.0.

A more detailed description of the actual Printed Circuit Boards, Components and Interconnections is contained in Figure 2.2.1, Cable Diagram.

The two of these diagrams together describe the signal/data flow within the Model 8000, as well as which cable, connector and boards are associated with a certain function.

The Model 8000 circuitry is seen to reside on five printed circuit boards, specifically, the Transformer Board, the Regulator Board, the Display Board, the Sensor Board and the

Processor Board. Each of these is discussed in general in this section and in more detail in the associated sub-sections.

3.2.2 TRANSFORMER PCB/AC LINE CIRCUIT

See Schematic; Figure 2.3.0, Assembly, Figure 2.3.1 and Bill of Material Table 2.3.2.

3.2.2.1 LINE CORD

Power is supplied to the pump through a Hospital Grade plug and line cordset. The cordset is terminated at the chassis in an A.C. input receptacle, allowing the cordset to be replaced if damaged. The pole clamp assembly is provided with a mechanical retention device, preventing removal of the line cord from the Pump, except with a screwdriver, to prevent accidental loss of the line cord.

3.2.2.1.1 LINE CORD AND INPUT VOLTAGE SELECTOR

Power from the AC line enters the Model 8000 Infusion Pump through the line cord and A.C. Power Entry Module, as shown on Figure 2.2.1, the Cable Diagram. The AC line connection to the Transformer Board is made through 7W1, the brown "line" wire and 7W2, the light-blue "neutral" wire. These connections are made with double insulated wire.

On entering the Transformer Board, line power is applied to the Voltage Selection connectors, as seen in the Schematic. If no jumpers are installed (fixed jumper traces are present) it results in parallel excitation of the dual transformer primary, for operation on 120 volts RMS nominal line voltage. Operation on nominal 240 volts RMS lines is possible by removing the fixed jumper traces and installing a jumper as seen on the schematic which selects series connection of the dual primary.

Fuses in the A.C. Power Entry Module must be selected for compatibility with the line voltage operation selected. Line fuses are as follows:

Fuses may be replaced only with the following parts:
For 120 Volt operation: Littelfuse 218.500 (0.5A Slo Blo)
For 240 Volt operation: Littelfuse 218.250 (0.25A Slo Blo)

Substitution of other fuses violates the Medical Device Certification of this Product, and may compromise Product Safety.

3.2.2.2 A.C. INLET MODULE FUSES

The A.C. Power Entry Module provides a chassis receptacle to allow for easy replacement of a damaged AC line cordset, houses the line fuses and provides a filter for control of line conducted interference into and out of the Pump chassis. Both Line and Neutral conductors from the Line Cord are fused, in accordance with IEC safety requirements.

Fuses may be replaced only with the following parts:
For 120 Volt operation: Littelfuse 218.500 (0.5A FB)
For 240 Volt operation: Littelfuse 218.250 (0.25A FB) Substitution of other fuses violates the Medical Device Certification of this Product, and may compromise Product Safety.

3.2.2.3 POWER TRANSFORMER

AC Line power enters the Pump through a 50/60 Hz, dual primary; double-bobbin wound Power Transformer. The Power Transformer steps the line voltage down to a low AC voltage, nominally 24 vrms, for rectification, filtering and subsequent regulation. The Power Transformer is mounted on the Transformer Printed Circuit Board, described further in Section

The Power Transformer is wound on double bobbins to guarantee minimum risk leakage current, maximize breakdown voltage and provide fault current creepage distance in accordance with the safety requirements of IEC Standard 601-2, CSA C22.2-125, and UL 544. The Transformer contains internal thermal cutouts to limit temperature rise in the case of a short circuit fault, either within the transformer or in the associated circuitry. Accordingly:

The Power Transformer may be replaced only with a CSA approved replacement transformer (Sigma p.n. 55001). Substitution of another transformer is a violation of the Medical Device Certification of this Product, and may compromise Product Safety.

3.2.2.4 SECONDARY VOLTAGE AND POWER INDICATOR

The secondary voltage of the Power Transformer is nominally 24 volts, and powers the Model 8000 through 7W3 and 7W4. Presence of AC power is indicated by energizing a light-emitting diode (LED) on the front panel. The small current required for the LED is supplied by D1, R1 and R2, and is a half-wave rectified, pulsating DC of less than 10 mA average current, or less than 20 mA peak.

Fuse F1 protects the transformer in the event of a catastrophic overcurrent drawn from the secondary. This fuse will ordinarily never need to be replaced and in the event that it opens, a serious failure elsewhere is indicated. Return the equipment for factory service if F1 opens, unless the reason for its failure is known for certain (i.e. an accidental short circuit during maintenance).

3.2.3 REGULATOR PCB/BATTERY CIRCUIT

See Schematic, Figure 2.4.0, Assembly, Figure 2.4.1, and Bill of Material, Table 2.4.2.

3.2.3.1 RECTIFIER, FILTER, REGULATOR

Low voltage AC from the power transformer secondary enters the Regulator Board at 6P1, and is rectified by bridge rectifier, D8. The raw DC is filtered by C16. The raw DC may vary between 22 to 39 Volts DC, and contain up to 4 Volts p-p of ripple, depending upon line and load.

A switched-mode, buck-topology regulator, U1, steps down the raw DC voltage to a nominal value of 15 volts. Due to component variations, the actual value of the regulated voltage may be between 14.9 and 16.2 volts. C10 - C15 provide low impedance decoupling for the switching ripple current of U1, which switches at 100 kHz. L1 is the filter inductor and D3 is the output catch diode for the regulator. R4 and R5 are the feedback resistors, which set the output voltage of the regulator. Filter capacitors C4 - C9 minimize ripple on the output voltage. Details of the operation of U1, a Linear Technology LT1076, may be found in Linear Technology Application Note 44.

The regulated 15 volts is summed with the battery voltage in diodes D4 and D6, to form the motor voltage supply, labeled VMOT. Diode summing allows the battery to take over

instantly upon loss of AC line voltage, and the battery to begin recharging immediately upon restoration of line voltage.

3.2.3.2 LOGIC VOLTAGE SUPPLY AND SWITCH

Supply voltage for the 5-volt logic in the Model 8000 Infusion Pump is regulated by a three-lead switching regulator, the Power Trends 78SR105, designated U2. The device is similar to the regulator described for the 15-volt supply, but all of the parts are contained in a single package. The switching frequency is 650 kHz, allowing a small inductor to be used.

Field effect transistor Q1 allows the logic supply to be turned on or shut off electronically from the processor board. This action may originate from the keyboard, the roller clamp or within the program. The keyboard switch may turn the power on or signal the microprocessor to turn the power off. The roller clamp may only turn power on (upon installation), while the program may only turn power off (in the event of low battery voltage or an OFF key actuation). A low level applied to the gate turns Q1 on.

3.2.3.3 Battery Charger

The Battery is a 12-volt lead-acid storage battery with a 2.5 Amp-hour capacity. When a new battery is fully charged, the battery will power the Model 8000 Infusion Pump for a minimum of 4.5 hours. The Battery is considered to be exhausted when its loaded voltage drops to 10 volts, at which time the system shuts down to prevent damage to the battery.

An exhausted battery begins to charge as soon as the line cord is plugged in. Q3 is biased on by R9 and R10, and draws a collector current of 10 mA through D2. The voltage drop of GaAs LED D2, roughly constant at 1.5 volts, forward biases the base of PNP transistor Q2. Because Q2 attempts to maintain a voltage of 0.9 volts (1.5-Vbe) across the emitter resistor, R6, the emitter current and therefore the collector current are constant. Q2 thus acts as a constant-current source charging the Battery, at a current of around 250 mA, or C/10, for the 2.5 Ah Battery.

Battery voltage is sensed by divider network R11, R12 and R13. D5 prevents discharge by the divider when line voltage is not connected. When the wiper of R12 rises to 2.5 volts, adjustable zener diode D7 draws anode current, partially shutting off Q3 and Q2, terminating constant current charging. The collector of Q2 then maintains a set voltage, charging in constant voltage mode until full charge is obtained.

R12 allows the constant voltage of the charger to be adjusted between 13.8 and 15.1 volts, accommodating the charging voltage needs of various batteries.

3.2.3.4 BATTERY PACK

Six (6) D-Cell starved electrolyte sealed lead acid storage batteries provide 4.5 hours of pump operation when fully charged. This can be used for either standby or portable operation.

3.2.3.5 REGULATOR PCB

Low-voltage AC from the Power Transformer is rectified to DC, filtered and voltage regulated by the Regulator Board. Regulation occurs in two steps.

A switched mode pre-regulator drops the voltage of the filtered DC to an intermediate level suitable for operating the pump motor and charging the battery. The battery is charged by the current-limited, constant-voltage technique at a rate of C/10. The motor is driven with a constant-current, switched-mode motor driver.

A second switched mode regulator provides the logic power voltage from the intermediate supply voltage.

3.2.4 DISPLAY PCB/AUXILIARY BUS

See Schematic, Figure 2.5.0, Assembly, Figure 2.5.1, and Bill of Material, Table 2.5.2.

3.2.4.1 DISPLAY PCB

The Display is made up of two, side-by-side, four- character, alphanumeric Light Emitting Diode Data Display Circuits, for a total of eight characters. Each LED matrix is 6.9 mm high (0.27 inches), and comprises a 5 (horizontal) by 7 (vertical) dot matrix. LED color is green. The display has the capability of 128 ASCII characters.

Details of the Display Board Assembly are found in Figure 2.5.1 and Table 2.5.2.

All data reports, alarm messages and user operating prompts (instructions) appear on the Display.

3.2.4.2 DISPLAY/AUX BUS INTERFACE

The data is transmitted from the Processor Board to the Display Board via a 20-conductor, 8-bit parallel data bus. The bus contains four address bits and two device select lines, allowing up to 32 read/write data locations to be defined. The Display Board utilizes nine locations, one for each of the eight characters, and the ninth for a bidirectional control register. The data bus connects to 3J1.

The Power Indicator LED is also housed on the Display Board, connected to 3J2. The LED illuminates the power indicator on the Keyboard whenever the AC line cord is plugged in.

3.2.4.3 LED Displays

The Display Board holds two, 4-character ASCII Alphanumeric LED Data Displays. Each Character is made up of a 5x7 matrix of green light emitting diodes. Characters are 0.27 inches high and spaced on 0.25 inch centers. Any of 128 ASCII characters may be written to the display, in any of the eight character positions, in random order.

3.2.5 SENSOR PCB

See Schematic, Figure 2.6.0, Assembly, Figure 2.6.1, and Bill of Material, Table 2.6.2.

The Sensor Board provides additional printed circuit board area to house the interface circuits for the temperature, air, roller clamp, drop/flow and pressure/occlusion sensors. Each of these sensors operation depends upon a transducer element to change the physical quantity being measured into an electrical analog voltage, along with circuitry to standardize the voltage for use by the processor. Each of these is discussed in its respective sensor section elsewhere in this theory of operation.

3.2.6 PROCESSOR PCB

See Schematic, Figure 2.6.0, Assembly, Figure 2.6.1, and Bill of Material, Table 2.6.2.

The Processor Board contains the 68HC16 Microprocessor and the Random Access Memory (RAM) and Programmable Read Only Memory (Program PROM) necessary to run the control program of the Model 8000 Infusion Pump. In addition, the Keyboard Interface, Display Interface, Motor Controller and Speaker Driver occupy the Processor Board.

3.2.6.1 Microprocessor

Central to the operation of the Model 8000 Infusion Pump is the Motorola MC68HC16Z1 Control Adapted Microprocessor (see Figure 2.6.0). The internal makeup of the 68HC16 includes a 16-bit processing unit, capable of clock rate as high as 16 MHz, surrounded with an array of counters, timers, analog-to-digital converter, general purpose input/output, multi-priority interrupts and data bus interface. The 68HC16 is housed in a 132-pin Plastic Surface Mount Package, Designated UNN1 on the Assembly Drawing, Figure 2.6.1. The 68HC16 is seen to occupy the center of sheet 1 on the Schematic, surrounded with peripheral circuits providing the functions necessary for operation of the Model 8000 Infusion Pump.

Starting at pin 1 of the 68HC16 Processor and following the pin numbering counter-clockwise, operation of the processor may be discussed. Detailed descriptions of the other parts on the Processor Board will follow. Pin 3 is the output of a timer set to the frequency of the alarm tone. The tone is a square wave and drives the alarm volume control IC, U7. Pins 6, 7 and 127 are I/O pins used to increment and decrement the volume control, U7.

Pins 4,5,13 and 14 are outputs. Pin 4 controls the Staff Call circuit, pin 5, the DC On/off function and pins 13 and 14, device selection for the Syringe and Roller Clamp Sensors.

Pins 10, 11, 12, 15 and 16 are used to form the Queued Serial Bus for the serial EEPROM and the RTC.

The Serial Receive Data and Transmit Data occupy pins 17 and 18, and drive the Serial Communication Interface, U49.

Pins 19 through 39 form the System Address Bus, A18- A1. A18 is unused, while A0 originates on pin 90.

The Analog Inputs, with eight separate A/D converter channels and reference voltage inputs occupy pins 42 through 53.

Standby voltage from the lithium Backup Battery is applied to pin 54. This source also maintains the Real Time Clock when power is shut down. The battery is protected from chance contact with other voltage sources by D1 and from short circuits by R3. Projected battery life for the Lithium Battery is at least four years of continuous backup, probably nearer five or six years with normal use, since the battery is not consumed while unit power is on.

The 32,768 Hz clock input is on pin 57. Decoupled power for the internal clock synthesizer is supplied through pin 56. The phase detector filter capacitor for the synthesizer is connected at pin 60. The internal clock frequency is set by the program by the values loaded into the synthesizer dividers. The synthesized clock frequency may be monitored at pin 63 of the Processor, or on 1J9-14.

The External Debugging Port occupies pins 63 through 71 of the Processor, and are available at the Test Port Connector, 1J9. This port is intended to allow access to the processor for test and calibration purposes, under the control of a PC.

The Lever latch is controlled by pin 73, configured as an output, while the status of the Lever is monitored by pins 72 and 79 configured as inputs.

System interrupts are applied to the processor on pins 75 through 78. Interrupt acknowledges return on pins 119 through 123.

The Write line is on Processor pin 80. Pin 81 through pin 89 and 182 to 131 are used as miscellaneous Input Port lines, for example, monitoring the status of the PCA input and flow detector installation. Most of the Input port is spare.

The balance of the Processor pins are devoted to Data Bus (Pin 91 to pin 109) and Device Select Lines (Pin 110 to pin 118).

3.2.6.2 POWER SWITCHING CONTROL

The power switching control allows the DC power to the Model 8000 Infusion Pump circuit boards to be turned on or off electronically. U19 is powered from the standby supply, VSTBY, continuously. Operating the On/Off key on the keyboard, or installing a roller clamp, grounds one of the inputs to U51 (A), forcing the output high. The clock input of U19 (A) rises and the flip-flop toggles, turning on Q2, Q13, Q14 on the Processor Board and Q1 on the Regulator Board. Logic power and motor power are thus applied to the circuitry.

The output of U51 (A) is applied to the set input of U19 (B) which will turn off the alarm backup power U54 had it previously been turned on by the supervisor circuit. Operating the On/Off key again has no further effect upon U19, but signals the processor through the keyboard encoder that the power should be turned off. The microprocessor will then apply a low level to U20 pin 5 and through U51 clears the output of U19 (A) turning Q2 off and shutting off the power to the circuitry. The !PWROFF signal from the processor allows the processor to turn power off, but logically can not turn power on when it has no power. Q14 switches current-limited battery power to the voltage divider made up of R88, R89 and R90. The divider allows the processor to monitor the battery charge state at Analog Input 5. Shutting off the divider prevents discharging the battery during storage; if the line cord is not plugged in. 1J1 connects the Processor Board to the power harness.

3.2.6.3 STATIC RAM AND PROGRAM PROM

Program storage occupies U2, the Programmable Read Only Memory (PROM). The PROM is organized as 65,536 words (128k bytes) of 16 bits, and may be doubled to 131,072 words (256k bytes) by installing a more dense memory package. Because the processor reads program memory by word, the byte control bit of the address (A0) is not used on the PROM. PROM chip select (!PCS)is derived from the !CSBOOT line of the Processor.

Data storage is accomplished by U1, the Static Random Access Memory (SRAM). The SRAM is organized as bytes of 8 bits, addressed as bytes (by A0), with a capacity of 131,072 bytes (128k bytes) in a 32-pin SOIC, or 65,536 bytes (64k bytes) in a smaller 28-pin SOIC. Although the program may never need the storage capacity of either of these packages, they are the industry standards, and the migration path is provided so that the product life time of the Model 8000 is not dictated by the seemingly rapid component turnover in the IC industry.

3.2.6.4 ELECTRICALLY ERASABLE PROM

Electrically Erasable Programmable Read Only Memory, or EEPROM, provides the Model 8000 with a medium for the storage of data which must be changed on occasion, but maintained most of the time. This might include pump configuration data or the history buffer log.

EEPROM is read or written by the processor through the Queued Serial Bus. Data to the EEPROM is applied to U15-3, the Data In line of the EEPROM from UNN1-11, the MOSI line of the Processor. Returning data, on the MISO line, moves from U15-4 to UNN1-10.

The Processor clocks the data transfer by pulsing UNN1-12 and U15-2. The EEPROM select is decoded by U22-10, from the states of UNN1-15 and 16.

3.2.6.5 RTC/Clock and Supervisor Circuit

The Real Time Clock, U4, provides the Model 8000 with a time of year timekeeping function, so that the history log may be time-stamped. Time is maintained during unpowered storage by the lithium back-up battery. The 32.768 kHz clock for the Processor is supplied by the RTC, when the +5-volt logic power is turned on, and the power-up reset is asserted until the logic supply has been stable for about one second.

Time is read or set by the processor through the Queued Serial Bus. Data to the RTC is applied to U4-5, the MOSI line of the RTC from UNN1-11, the MOSI line of the Processor. Returning Data, on the MISO line, moves from U4-6 to UNN1-10. The Processor clocks the data transfer by pulsing UNN1-12 and U4-4. The RTC select is decoded by U22-11, from the states of UNN1-15 and 16.

The processor must pulse the RTC select line every 200 ms (5 PPS) to prevent the Supervisor Circuit from sounding an alarm and shutting off power to the micro processor. This audio is an indication of processor failure, produced by counter U16, which continuously counts the independent 32 kHz clock. A pulse on the RTC select line is synchronized with the clock by the two flip-flop stages U17B and U18A, and applied to the counter reset. Failing to reset the counter will start a pulse modulated 2 kHz tone at 2 bursts per second, within 250 ms of the last reset pulse.

3.2.6.6 Analog Input Channels

Eight Analog-to-Digital Converter Inputs give the Processor access to the analog signals necessary to the operation of the Model 8000 Infusion Pump. A 4.096 volt reference is established for the A/D Converters by adjustable zener diode, D14. This also serves as the excitation source for the Thermistor (TH1).

Analog inputs are assigned as follows:

- **Analog 0, Air/Upstream Occlusion, Sensor 1**
- **Analog 1, Temperature (Thermistor, TH2)**
- **Analog 2, Downstream Pressure**
- **Analog 3, DS Occlusion Supply (.5Vex)**
- **Analog 4, Air/Upstream Occlusion, Sensor 2**
- **Analog 5, 12V Battery Voltage (.2VBAT)**
- **Analog 6, Temperature**
- **Analog 7, Motor Supply Status, AC Line Status (.2SWVMOT)**

3.2.6.7 PUMP TEMPERATURE

The pump temperature is monitored by U69 on the Processor PCB. The alarms that may occur due to a temperature change are as follows:

LOW TEMP: The pump's temperature sensor has detected that the pump temperature is below 40°F. Allow the pump to reach a minimum of 68°F before subsequent operation. This alarm will reset when temperature goes above 40°F.

HIGH TEMP: The pump's temperature sensor has detected that the pump temperature is above 150°F. Allow the pump to return to below 85°F before subsequent operation. This alarm will reset when temperature goes below 150°F.

3.2.6.8 SPEAKER DRIVER/VOLUME CONTROL

The alarm tone originates as a square wave output from UNN1-3, which is the output from one of the timer functions of the Processor. The Tone is applied to the high end of U7 (Pin 3) which is a CMOS electronic voltage divider. U7 operates analogously to a manual volume control, but the control rotation is replaced by an electronic counter turning field effect transistors on and off, to change the resistance of a 100-step resistor divider.

The sign of the volume change (increase or decrease) and slope of the change (how quickly it changes) are controlled by three outputs from the Processor.

The alarm tone is amplified and applied to the speaker by power amplifier U8, as is the supervisor tone when active.

3.2.6.8.1 SPEAKER

A 1-inch, plastic cone speaker allows the Model 8000 Infusion Pump to alert an operator to a malfunction via an auditory alarm.

The audible alarm tone accompanies all displayed alarm messages. Tone volume is selectable by the user, with a key sequence on the Keypad. The tone may be silenced for a period of two minutes from the Keypad, while the alarm message continues to be displayed.

3.2.6.9 DISPLAY/AUXILIARY INTERFACE

The Display/Auxiliary Bus is a general purpose, eight-bit extension of the system data bus. Eight bi-directional data lines are buffered by U14 allowing data to be written or read on the Aux Bus, by the Processor. Four address lines and two device selects are buffered by U13, allowing thirty-two locations to be defined on the bus. There is also an interrupt level (IRQ4) assigned to the Aux Bus.

The Display/Aux Bus is presently used for the Display Board and the Sensor Board.

3.2.7 KEYBOARD

The Keyboard is a 21-position membrane key switch matrix. The surface of the Keypad is PET Polyester film, providing resistance to all common hospital cleaners and disinfecting solutions.

Details of the Keyboard Assembly and functional key assignments may be found in Figure 2.14.0, Schematic, Figure 2.14.1, 8000 Keyboard Assembly Drawing and Figure 2.14.2, 8000 Plus Keyboard Assembly.

3.2.7.1 KEYBOARD INTERFACE

A keyboard of up to 40 keys, in a 4-by-10 key matrix, may be accommodated by the keyboard encoder comprised of U10 and U12. The 74C923, U10 is the Keyboard Encoder proper, and converts a single key closure in the x-y switch matrix into a binary code which is presented to data buffer U11. Key bounce and multiple closures are eliminated by U10. Five additional "y" inputs are added to the switch matrix by U12, doubling the capacity of the Encoder from 20 keys to 40 keys.

When a key is pressed, the Encoder, U10 begins a time out to allow the key to stop bouncing. At the end of the time-out, the key code appears at the outputs, and the data available line (U10-13) rises. The rising data available line sets flip-flop U18A, entering an interrupt on the IRQ3 level. When the Processor responds to the interrupt, the acknowledge

line, IACK3, falls and clears the interrupt. The processor then reads the keycode data by asserting DSEL2, strobing the data onto the system data bus via U11.

3.2.8 TEST PORT, SHAFT SENSOR, FLOW SENSOR and LEVER LOCK CONTROL

See Assembly, Figure 2.8.1, and Bill of Material, Table 2.8.2.

The Test Port, 1J9, contains all of the signals used by the MC68HC16Z1 Processor for its internal debugging mode. The intention is to allow access to the processor via a PC terminal, for automated test and calibration procedures.

The Shaft Sensor is a magnetically activated Hall- effect device, which produces one pulse for each rotation of the pump shaft. The sensor pulse sets flip-flop U5A, entering an interrupt on IRQ1. The processor clears the interrupt by asserting IACK1, and enters any operation dictated by the interrupt service routine. Monitoring pump rotation allows the processor to determine whether the pump has stalled due to a broken belt or other reason.

The flow sense signal produces a similar response on U5B, IRQ2 and IACK2.

The Lever Release Solenoid is controlled from Processor output PF6, UNN1-73, which drives a high current switching FET, Q12. Energizing the solenoid opens the Lever lock, allowing the Lever to open.

The status of the Lever is monitored by two Hall-effect devices, through Processor inputs and PF7, pins and UNN1- 72, respectively.

3.2.9 BACK PANEL/SERIAL INTERFACE CONNECTOR

A 9-pin, D-subminiature connector located on the rear panel of the pump provides for connection of devices to access various input and output functions of the pump. Accessories and options include an opto-electronic flow detection device, a nurse call output, an RS-232 based serial data interface and planned future expansion options.

3.2.9.1 FLOW SENSOR AND INTERFACE

The Flow Sensor which connects to the SIGMA 8000 attaches to the drop chamber of the I.V. set. It consists of a housing enclosing an IR LED emitter with two IR phototransistors located opposite across the drop chamber to register the drops, and an integral interconnect cable.

The LED is pulsed at 2 kHz, at a 12.5 per cent duty cycle. The signals from the phototransistors are demodulated by U46, a quad analog switch, which is used as a synchronous demodulator.

A sudden drop in the output level of either phototransistor causes a negative pulse at the input of differentiator U47B. The pulse is inverted by U47B, and the edges squared by U37C. The DROP signal sets flip-flop U5B, which interrupts the processor on IRQ2.

Installing a sensor pulls up the LED drive line above five volts, switching comparator U47A to its high state. The high Logic State is transferred to the Processor FLOWINStalled line through U37D.

3.2.9.2 NURSE CALL

The Nurse Call consists of a relay closure, with an isolated output stage. The relay output is bi-directional to allow AC signals to be switched, or DC signals of indifferent polarity. The back panel connector contacts used for this function are pins 1 and 4.

Refer to Section1 1.4.4 for Staff Call Contact Ratings.
Pump alarms that activate Nurse Call are:

- Air In Line
- Upstream (Proximal) Occlusion
- Downstream (Distal) Occlusion
- Motor Speed Error
- "Plug In" Alarm (Battery Dead)
- Infusion Complete
- Flow Sensor Removed
- Empty Bottle Alarm

3.2.9.3 SERIAL COMMUNICATION INTERFACE

The serial interface is compatible with EIA/RS-232 Serial Communication Interface bus. The serial interface allows Pump status to be monitored and history information access by an external host computer system. Changes in the pump operating status can only be made from the Keypad, not from the serial interface.

The Serial Transmit Data and Receive Data from the Processor are converted to EIA/RS-232 levels for transmission by the Serial Communication Interface, U49. The interface IC contains internal charge pumps to generate +12v and -12v for biasing the transmitter and receiver stages.

The transmit and receive lines exit through the Sensor Interface via J12, to the Serial/Flow Connector, J12A, on the rear panel of the Model 8000.

P/N 44000 Revision: M

REVISION HISTORY

Level	Date	Description of revision
P01	2/28/96	Preliminary copy for trial distribution (original 1st issue)
P02	6/10/96	Updated section 1.10.1 "FIX ME" codes
P03	11/11/96	Update sections 1.2, 1.3, 1.4, 1.6, 1.7, 1.11 and tech. drawings.
P04	6/26/97	Update sections 2.6,2.7,2.10,2.11,2.12, 2.13,2.14,2.15,1.11, add ICL 35001, opt541 & opt542.
A	11/3/98	Initial release
B	9/00	Updated to include information for newest software release V3.29
C	10/10/00	Updated to include information for newest software release V3.30.00
D	5/15/01	Updated to include information for newest software release V3.40.00 also updated description of Nursecall.
E	9/01/01	Updated to include information for the newest software release V3.41.00
F	4/16/02	Updated to include 8000 *Plus* references. SOP 11089 to Rev.B
G	5/16/03	Updated drawings and procedures, added information related to Drug Error Prevention and updated user and biomed options tables.
G1	9/234/03	Preliminary – changes related to DEP
G2	10/14/03	Preliminary 2 – updated graphics, made corrections based on review of G1
G3	4/28/04	Preliminary - Made changes per markups of G2, corrected grammer where indicated
H	9/13/04	Incorporated changes G1 – G3
J	5/13/05	Updated Dose Mode Displays, changed Abbott to Hospira, updated drawings for changes made since last Service Manual update, added Biomed Option 291. NOTE: Revision I will not be used due to the similarity to the #1.
K	11/2/05	Reformatted Table of Contents, updated 6.6 of ITP 35001PM to run at high pressure, fixed grammatical errors, added R70 to figure 2.6.2, changed P/N on figure 2.9.2 and updated Rev. levels of drawings
M	6/13/07	Added tests for 8002 pump (steps 6.3 and 6.9) to chapter 1.5. Preventative Maintenance Updated Preventative Maintenance Check Off Sheet